F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (*admitted pro hac vice*)
Aaron P. Maurer (*admitted pro hac vice*)
Rachel Shanahan Rodman (*admitted pro hac vice*)
Adam D. Harber (*admitted pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P.,

Counterdefendants.

CASE NO.: 08-CV-0133 RMW

DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

REDACTED VERSION

Date: April 21, 2008
Time: 2:00 p.m.
Courtroom: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES AND REGULATIONS

INTRODUCTION

Plaintiffs' request for a preliminary injunction should be denied. Defendant SenoRx, Inc. ("SenoRx") markets a device used to treat women with breast cancer, called the Contura MLB™ ("Contura"). The Contura represents a significant advance in the field of balloon brachytherapy. Its technology and design open the possibility of balloon brachytherapy – an important treatment option – to women who otherwise are not treatable by existing prior-generation balloon brachytherapy devices. These existing devices include one sold by Plaintiffs, under the tradename "MammoSite."

[redacted]

Plaintiffs' request for a preliminary injunction not only lacks urgency, it lacks merit. SenoRx will show: (1) Plaintiffs are not likely to succeed on the merits, as the asserted patent claims are not infringed and invalid, or, at the very least, there exists a substantial question as to whether the Contura infringes any valid claim of the patents-in-suit; (2) the proposed injunction will harm the public interest because the Contura safely and effectively treats women the MammoSite cannot; (3) Plaintiffs' alleged "irreparable harms" are anything but, as evidenced by, *inter alia*, Plaintiffs' grant of a license of the very patents at issue to a competitor in the field; and (4) the hardships to SenoRx outweigh any alleged harm to Plaintiffs. Consequently, Plaintiffs' request for the extraordinary relief of a preliminary injunction should be denied.

BACKGROUND

Balloon catheter breast brachytherapy has real advantages in targeting the tissue needing treatment, thereby minimizing the potential for side effects. Declaration of Douglas Arthur, M.D. ("Arthur Decl."), ¶¶ 14-20; Declaration of Philip Z. Israel, M.D. ("Israel Decl."), ¶¶ 21-25, 27. It also can be completed in just a few days with less trauma to the patient's breast than other methods. Arthur Decl. ¶¶ 14-20; Israel Decl. ¶ 12. [redacted] Declaration of Aaron P. Maurer ("Maurer

Decl.")[1], [redacted]. The general structure and use of the MammoSite and Contura are the same. Both devices consist of a catheter body with a balloon on the end. The Contura is pictured below, and a detailed description of the Contura's structure is found in ¶ 9 of the Declaration of William F. Gearhart ("Gearhart Decl.").

The catheter body has either a single lumen[2] (MammoSite) or multiple lumens (Contura) into which a radioactive seed may be inserted for treatment purposes by a machine called an "afterloader." Arthur Decl. ¶¶ 25, 27-28, 31-32. In use, the devices are inserted into a lumpectomy cavity of a woman, where the balloon portion is inflated with a contrast fluid to hold it in place and conform the cavity to the balloon shape. *Id.* ¶ 21. A CT scan of the device *in situ* is then made, and a physician and physicist determine how to best deliver radiation to the patient. *Id.* ¶¶ 22-23. The ideal dose profile delivers 100% of the target dose of radiation to the target tissue surrounding the cavity while minimizing the exposure of other tissues (especially sensitive tissues such as the skin and ribs). In practice, the ideal dosing profile is difficult to achieve, as the location of the lesion may be too close to the skin or ribs, or the cavity may not match the shape of the balloon. Israel Decl. ¶ 18-19. After a dose plan is optimized and approved, the afterloader is connected to the catheter by the lumen(s) at the proximal end of the device. Arthur Decl. ¶¶ 25-26. The radiation source is inserted into the device's lumen(s) by the

[1] All exhibits ("Ex.") referenced herein are exhibits to the Declaration of Aaron P. Maurer, unless otherwise specified.

[2] A lumen is a hollow tube. *See* Ex. 2 (Merriam-Webster's Dictionary), at 692 (defining lumen as "the bore of a tube (as of a hollow needle or catheter)"). In addition to the lumen(s) into which a radioactive source is inserted, both catheters also have an additional lumen leading to the balloon portion of the device. This lumen allows for the inflation and deflation of the balloon. The Contura has one additional lumen connecting to suction ports at the distal end of the device.

afterloader, and radiation is delivered at precise locations along the distal end of the lumen(s) by pausing and moving the radiation source according to the plan. The radiation source then is withdrawn back into the afterloader. *Id.*

Despite their similarities, the Contura offers significant advantages over the MammoSite. Arthur Decl. ¶¶ 31-37; Israel Decl. ¶¶ 20-25. The MammoSite has only a single treatment lumen, which is centrally located in the balloon. This design can preclude treatment of certain women, such as those with small breasts or whose tumors are located too close to the skin or near the ribs. Arthur Decl. ¶ 30; Israel Decl. ¶¶ 22, 32. The Contura, on the other hand, has five lumens – one central and four offset – into which the radiation source may be inserted. This allows the radiation dose to be tailored by positioning the radioactive seed at locations offset from the center of the Contura balloon to "push" or "pull" the resulting dose. Arthur Decl. ¶ 32; Israel Decl. ¶ 21. Physicians have found this flexibility to offer great advantages in treating patients with balloon brachytherapy. The Contura has allowed them to treat many women who could not be treated with Plaintiffs' devices and to achieve closer to ideal-dosing in others. Arthur Decl. ¶¶ 31-37; Israel Decl. ¶¶ 21-25, 32-33. The advantages of the Contura are but one of many reasons Plaintiffs' request for a preliminary injunction should be denied.

ARGUMENT

A preliminary injunction is a "drastic and extraordinary remedy that is not to be routinely granted." *Nat'l Steel Car, Ltd. v. Canadian Pacific Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004). To obtain such "extraordinary relief," Plaintiffs must establish: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in their favor; and (4) the injunction's favorable impact on the public interest. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *cf. eBay, Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 391 (2006).

Here, Plaintiffs fail to satisfy the foregoing factors, and no injunction should issue. Plaintiffs assert infringement of two claims: claim 36 of U.S. Patent No. 6,413,204 (the "'204 patent"); and claim 1 of U.S. Patent No. 6,482,142 (the "'142 patent"). As set forth below, Claim 36 is not infringed and is invalid over the prior art. Claim 1 of the '142 patent likewise is

not infringed and is invalid over the prior art, and also is invalid because it recites an inoperable invention. Moreover, continued availability of the Contura is in the public interest and does not irreparably harm Plaintiffs, and the balance of harms likewise supports denial of Plaintiffs' request for an injunction.

I. PLAINTIFFS CANNOT SHOW A REASONABLE LIKELIHOOD OF SUCCESS ON THE MERITS.

To establish a reasonable likelihood of success on the merits, Plaintiffs must show that SenoRx infringes a valid claim of Plaintiffs' patents-in-suit. *Amazon*, 239 F.3d at 1350. A "substantial question concerning either infringement or validity" precludes Plaintiffs from satisfying this standard. *Nat'l Steel Car*, 357 F.3d at 1334. As to validity, the question is not whether SenoRx will prevail at trial, but whether Plaintiffs' patent is "vulnerable" to an invalidity challenge. *Amazon*, 239 F.3d at 1359; *see also Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007) (less than clear and convincing evidence will suffice); *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) (same). Here, the evidence presents a substantial question as to the validity and infringement of the asserted claims.

A. The '204 Patent – Claim 36 Is Not Infringed and Is Invalid.

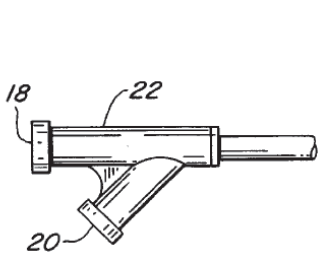
This Court previously construed the '204 Patent in *Xoft, Inc. v. Cytyc Corp.*, No. C-05-05312 RMW (the "*Xoft* case").[3] *See* Ex. 3 (Cl. Constr. Order). Plaintiffs assert that application of the Court's prior claim construction necessitates a finding of infringement in this case. Pl. Br. at 10. That is incorrect. This Court's prior construction shows SenoRx does not infringe claim 36, and that claim 36 is anticipated by the prior art.

[3] The claim construction in the *Xoft* case was based on arguments made in part by a different party with respect to a different allegedly infringing device. Because the SenoRx device does not infringe based on the Court's construction in *Xoft*, SenoRx accepts the construction for purposes of this expedited proceeding, but it reserves the right to request that the Court construe certain of the terms of the '204 patent at a later date.

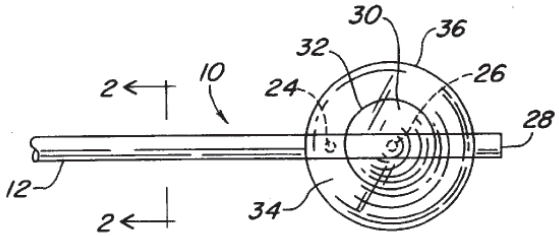
1. The Contura Does Not Infringe Claim 36 of the '204 Patent as It Lacks an "Inner Spatial Volume."

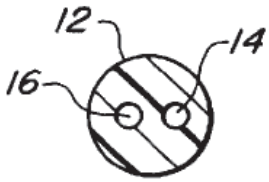
Plaintiffs' proposed application of this Court's prior construction of the "inner spatial volume" claim limitation of claim 36 is contrary to this Court's claim construction order, and the disclosure and claims of the '204 patent. Correctly applied, this Court's prior construction means the Contura does not infringe claim 36.

The '204 patent claims a balloon catheter-based brachytherapy device. Several specific embodiments of that device are described in the patent specification. As this Court observed in the *Xoft* case, "[i]n most embodiments of the invention disclosed in the patent specification, the inner spatial volume is a region of space surrounded by an outer spatial volume that is defined by a closed inflatable chamber." Ex. 3 (Cl. Constr. Order), at 4. This configuration is depicted, for example, in the "balloon within a balloon" embodiment shown in Figures 1 and 2.



'204 Patent, Figure 1





'204 Patent, Figure 2

Ex. 4 ('204 patent), at Fig. 1, Fig. 2. This Court also recognized, "however, the patentee drafted the claims in such a way as to make clear that the inner spatial volume was not necessarily so limited." Ex. 3 (Cl. Constr. Order), at 5 ("[I]nstead of having the inner spatial volume 30 defined by a generally spherical polymeric film wall as at 32, the catheter body member 12 may have a solid spherical radiation emitting material 44 as the inner spatial volume 30." (emphasis added)); *see* Ex. 4 ('204 patent), at 4:44-5:12.

All of the claims of the '204 patent, including claim 36, recite an "inner spatial volume." In the *Xoft* case, this Court discussed the disclosure of the patents in detail, and concluded that "[i]n all embodiments . . . the boundary of the inner volume is either a polymeric film wall or the edge of a solid sphere." Ex. 3 (Cl. Constr. Order), at 5; *see also id.* at 16. Accordingly, this

Court construed an "inner spatial volume" to be "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere." *Id.* at 5, 16.

However, Plaintiffs now seek to dissociate the Court's construction – which was firmly grounded in the claims and disclosure of the patent – from its reasoning by asserting that the lumens of the Contura are an "inner spatial volume." Plaintiffs state that "[e]ach of the five treatment lumens inside the Contura MLB constitutes an inner spatial volume . . . . Alternatively, the five treatment lumens and the area within the balloon between and surrounded by those lumens together define one inner spatial volume." Pl. Br. at 13. But Plaintiffs' argument is refuted by the '204 patent and this Court's claim construction ruling in *Xoft*.

First, the '204 patent makes clear that lumens and the "inner spatial volume" are different things. For instance, in its description of the "balloon-within-a-balloon" embodiment, the patent explicitly labels the inner spatial volume as item number 30, defined by polymeric film wall 32. That same embodiment separately contains lumens, labeled as numbers 14 and 16. The lumens are not described or depicted as being the inner spatial volume, but instead are parts of the tubular catheter body that are in "fluid communication" with the inner spatial volume:

> A surgical instrument 10 . . . is illustrated in Fig. 1. Surgical instrument 10 includes a **tubular body member 12 having first and second lumens 14 and 16** (FIG. 2) extending from proximal ports 18 and 20 in a molded plastic hub 22 to inflation ports 24 and 26 formed through the side wall of the tube 12 and intersecting with the lumens 14 and 16, respectively.
>
> Affixed to the tubular body 12 proximate the distal end 28 thereof is an **inner spatial volume 30** which may be defined by a generally spherical polymeric film wall 32. The interior of the inner volume 30 is in fluid communication with the inflation port 26.

Ex. 4 ('204 patent), at 3:49-61 (emphasis added). Claim 36 maintains the distinction between the catheter body (element [a], having lumens as part thereof) and the inner spatial volume (element [b]).

The same is true for the solid radionuclide embodiment. Instead of equating the inner spatial volume and the lumen, as Plaintiffs suggest, the patent plainly distinguishes between a lumen in the catheter body and the "inner spatial volume" inserted through that lumen:

> In a further embodiment, illustrated in FIG. 3, instead of having the inner spatial volume 30 defined by a generally spherical polymeric film wall as at 32, the catheter body member 12 may have a **solid spherical radiation emitting material 44 as the inner spatial volume 30**. . . . The solid radiation emitting material 44 **can be inserted through catheter 12** on a wire 46 . . . .

Id. at 4:44-48 (emphasis added). Plaintiffs' infringement contentions ignore the distinction in their own patent between the lumens of the device that are part of the catheter body, and the "inner spatial volume" of the device that is separate and apart from the catheter body. They are not the same thing.

Second, as this Court recognized in its claim construction ruling, the inner spatial volume must be "surrounded by" the outer spatial volume. The lumens in the Contura (as in the patent) do not meet this requirement. Instead, the five lumens in the Contura device are contiguous tubes that run from the external (proximal) end of the Contura device through to the end of the balloon at the internal (distal) end of the Contura device. They are not "surrounded by" the volume defined by the Contura balloon (i.e., the "outer spatial volume"), but instead extend out of the outer spatial volume. In this respect, the lumens of the Contura again are like the lumens of the '204 patent. *See id.* at 3:51-56 ("first and second lumens 14 and 16 . . . extending from proximal ports 18 and 20 . . . to inflation ports 24 and 26").[4] As these lumens extend beyond the "outer spatial volume," they cannot be (either individually or collectively) "an inner spatial volume."

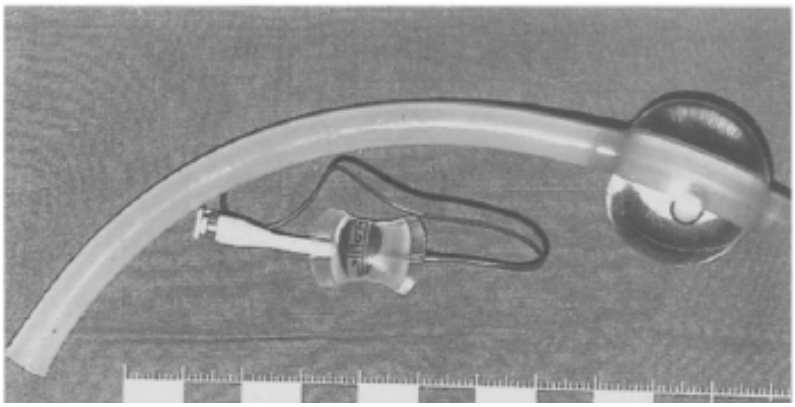
2. Claim 36 of the '204 Patent Is Rendered Invalid by the Prior Art.

Despite their assertions to the contrary, Plaintiffs did not invent brachytherapy using balloon catheters. Instead (if anything), they invented very particular embodiments of one such

[4] Plaintiffs incorrectly suggest there are two sets of lumens in the Contura – "radiation source lumens" that extend from the end of the device up to the balloon, and separate "treatment lumens" inside of the balloon. *See* Pl. Br. at 12-13. In fact, there is only one set of lumens in the Contura into which the radiation source is inserted, consisting of five tubes extending from one end of the Contura through to the other. *See* Gearhart Decl. ¶ 9; Gearhart Decl. Ex. 1 (picture of Contura MLB).

catheter. Given the broad interpretation Plaintiffs have assigned claim 36, there exists a wealth of invalidating prior art.

For example, claim 36 is anticipated by a 1990 article entitled "A New Technique of Brachytherapy for Malignant Gliomas with Caesium-137: A New Method Utilizing a Remote Afterloading System," authored by Ashpole, *et al.* ("Ashpole"). Ashpole describes the irradiation of a brain tumor site[5] using a modified endotracheal tube that has a catheter body with a lumen and a balloon at the far end. Ex. 5 (Ashpole), at 334 & Fig. 1 (below).[6]



Ashpole Figure 1

Ashpole inserted the balloon-end of the device into the patient's tumor cavity and filled the balloon with fluid "so that the inflated balloon filled the postsurgical cavity." *Id.* The patient was transferred to a radiotherapy center, and a radiation afterloader applicator was inserted into the central lumen of the catheter of the Ashpole device. *Id.* at 334-35. The afterloader was programmed to place a series of active and inactive spherical radioactive beads into the Ashpole catheter, locating them inside the portion of the lumen within the balloon in order to achieve the required dose for treatment of the margins surrounding the surgical cavity. *Id.* at 335-336. The

[5] The claims at issue in this proceeding are not limited to treatment of breast cancer, but are generic to "interstitial brachytherapy" in any tissue.

[6] Ashpole is discussed in detail in the Declaration of Dr. Colin Orton. See Orton Decl., ¶¶ 11-29.

dose delivered was chosen to effectively treat the tumor margins, while taking into account the tolerance of the surrounding tissue in order to minimize harm to healthy tissue. *Id.* at 336.

Accordingly, Ashpole anticipates every element of claim 36, as set out in the claim chart below.

Claim 36	Ashpole, "A New Technique of Brachytherapy . . . " (1990)
An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:	Ashpole describes an apparatus for interstitial brachytherapy. Ex. 5 (Ashpole), at 334 & Fig. 1; Declaration of Colin Orton, Ph.D. ("Orton Decl."), at ¶¶ 12, 14.
(a) a catheter body member having a proximal end and distal end;	The Ashpole device has a catheter body having proximal and distal ends. *See* Ex. 5 (Ashpole), at 334 & Fig. 1; Orton Decl. ¶¶ 12-13, 15.
(b) an inner spatial volume disposed proximate to the distal end of the catheter body member;	If a lumen is considered to be an "inner spatial volume," the Ashpole device contains an inner spatial volume at or near the distal end of the catheter. *See* Ex. 5 (Ashpole), at 334 & Fig. 1; Orton Decl. ¶ 13. Alternatively, Ashpole contains an inner spatial volume defined by the outside surface of a radionuclide bead in the Ashpole source train. *See* Ex. 5 (Ashpole), at 334-35 ("active bead . . . encapsulated in stainless steel to form a sphere") & Fig. 3; Orton Decl. ¶¶ 17-18, 22.
(c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and	The balloon disposed on the far end of the Ashpole device constitutes an outer spatial volume. *See* Ex. 5 (Ashpole), at 334 & Fig. 1; Orton Decl. ¶¶ 12-13, 16. If the balloon of the Contura surrounds an "inner spatial volume" by surrounding portions of the Contura lumens, the balloon of

Claim 36	Ashpole, "A New Technique of Brachytherapy . . . " (1990)
	Ashpole likewise surrounds an inner spatial volume. *Id.* Alternatively, the outer expandable balloon of the Ashpole device surrounds an "inner spatial volume" by surrounding any one of the radioactive beads in the source train. *See* Ex. 5 (Ashpole), at 335 & Fig. 3; Orton Decl. ¶¶ 12-13, 16-18, 22.
(d) a radiation source disposed in the inner spatial volume;	If a lumen is an inner spatial volume, a radiation source (radioactive bead) is disposed in the inner spatial volume of the Ashpole device. *See* Ex. 5 (Ashpole), at 335 & Fig. 3; Orton Decl. ¶¶ 17-18, 22. Alternatively, the interior of a radioactive bead satisfies this limitation. Orton Decl. ¶ 17.
wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.	Ashpole describes varying the balloon configuration, as well as the configuration of the radioactive sources with respect to the balloon, to achieve an acceptable dose in the target tissue, while reducing and preventing necrosis in healthy tissue. Ex. 5 (Ashpole), at 336 ("The dose . . . depends on the number and arrangement of sources as well as the balloon diameter . . . . The configuration of the balloon plays a key role in producing an acceptable dose distribution."); *id.* at 335 ("We aim to produce . . . . a total dose of 50 Gy to the tumour bed."); *id.* at 336 (the dose "takes into account the known tolerance of normal brain"); Orton Decl. ¶¶ 20-29. This means that the volumes are configured to produce a minimum prescribed dose to the target tissue while limiting the dose received by the healthy tissue proximate the expandable surface. *Id.*

* * *

Plaintiffs cannot show a substantial likelihood of success of proving that claim 36 is valid and infringed. The claim is not infringed by the Contura, for at least the reason that the Contura lacks an "inner spatial volume." Additionally, the claim is anticipated by (and obvious over) the Ashpole reference.

B. The '142 Patent – Claim 1 Is Not Infringed and Is Invalid.

The only other claim asserted by Plaintiffs in their Motion is claim 1 of the '142 Patent. The '142 patent, unlike the '204 patent, was not at issue in the *Xoft* case. However, Plaintiffs suggest the construction of terms in the *Xoft* case is relevant to the '142 patent, given the close relationship between the '142 and '204 patents. Pl. Br. at 11. SenoRx agrees. The application of the plain meaning of the terms in claim 1, especially in light of the Court's construction of related terms in the *Xoft* case, shows there is no infringement by SenoRx of claim 1 of the '142 patent, and that claim 1 is invalid.

1. The Plain Meaning of "Apparatus Volume."

The first element of claim 1 requires "an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated." Ex. 6 ('142 patent), at 8:63-67 (emphasis added). As an initial matter, this Court should construe "three-dimensional apparatus volume" consistent with its ordinary meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-14 (Fed. Cir. 2005) (*en banc*). This is not a situation where the inventor used an idiosyncratic term or where the plain meaning of the term is difficult to divine. *See id.* The inventors used common-place words to precisely define the meaning of the phrase in the claim itself. Plaintiffs concede this point, stating in their verified response to SenoRx's interrogatory on claim construction that "three-dimensional apparatus volume" should be construed according to its "Plain meaning (no construction necessary)." Ex. 7 (Pl. Resp. to SenoRx Interrs.), at 9 (emphasis added). The plain meaning of "three-dimensional apparatus volume" is the three-dimensional region of space within the expandable outer surface. This

region of space is "defin[ed]" by the "expandable outer surface" and "fill[s] [the] interstitial void created by the created by the surgical extraction." Ex. 6 ('142 patent), at claim 1, 8:64-65.

The concept of an outer "surface" defining a "volume" is consistent with this Court's claim construction in the *Xoft* case. In that case, Xoft asked the Court to equate the claim term "inner spatial volume" with either an "inner balloon" or a "spherical radionuclide." The Court declined to do so, stating:

> As Cytyc points out, **Xoft's construction conflates the boundary of the volume with the volume itself**. . . . In all embodiments of the invention disclosed in the '813 patent, the boundary of the inner volume is either a polymeric film wall or the edge of a solid sphere.
>
> ***
>
> The "outer spatial volume" is also explained in a similar manner; it is "defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume." '204 patent, col. 8, ll. 22-25. **Xoft again confuses the concepts of a volume with the boundary of a volume.**

Ex. 3 (Cl. Constr. Order), at 5, 17 (emphasis added). The Court thus construed the "volumes" at issue to be "regions of space" bounded or defined by some physical structure, *i.e.*, the surface of a balloon or outer surface of the radionuclide. *Id.*

This claim construction is the one Plaintiffs pressed the Court to adopt in the *Xoft* case. Discussing the "inner spatial volume" limitation of the related '813 patent, Plaintiffs cited the dictionary definition for "volume" and argued that:

> More fundamentally, **Xoft confuses the tangible structure that defines the inner spatial volume with the volume itself.** The specification provides that the inner spatial volume 30 "may be defined by a generally spherical polymeric film." **The film defines the boundary of the volume but the volume is the region of space within that boundary.** (Exhibit C to the Declaration of Henry C. Su (American Heritage College Dictionary ("AHC")) at 1513.)

Ex. 8 (Pl. Cl. Constr. Br.), at 9 (emphasis added). Plaintiffs reemphasized the same point in the construction of the terms of the '204 patent: "The film defines the boundary of the volume but the volume is the region of space within that boundary." *Id.* at 18.

The Court's construction and Plaintiffs' arguments in the *Xoft* case match the language of claim 1 of the '142 patent. Claim 1 requires "an expandable outer surface defining a three-

dimensional apparatus volume," that is, a three-dimensional volume (region of space), defined by and within the outer surface of the balloon. This "three-dimensional apparatus volume" is configured to "fill" the interstitial void created by the surgical extraction of diseased tissue. Plaintiffs apparently agree, as they have explicitly so stated in their infringement contentions in their brief in this case. *See* Pl. Br. at 17 ("The outer surface of the inflatable spherical Contura MLB . . . defines the three-dimensional apparatus volume that fills the resection cavity." (emphasis added)).

2. The Contura Does Not Infringe Claim 1 of the '142 Patent as It Lacks a Radiation Source "Located so as To Be Spaced Apart from the Apparatus Volume."

Claim 1 requires that the radiation source of the device be "located so as to be spaced apart from the apparatus volume." Plaintiffs admit that the radiation source of the Contura is located inside the expandable outer surface of the device. Pl. Br. at 18. Because the expandable outer surface defines the three-dimensional apparatus volume – that is, the volume is the region of space within the expandable outer surface – the Contura therefore does not infringe the claim as a radiation source that is inside a volume plainly is not "located so as to be spaced apart from" the volume.

Recognizing this, Plaintiffs now seek to re-write the claim to read a radiation source "located so as to be spaced apart from the apparatus surface." They do this by equating the apparatus volume with the surface that defines that volume:

> All of the treatment lumens [of the Contura] are spaced apart from the apparatus volume (e.g., **not touching the interior surface of the expandable surface of the balloon**) . . . .

Pl. Br. at 18 (emphasis added).[7] Plaintiffs' attempt to re-write the claim by redefining the volume as the surface must fail. *See Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1356-57 (Fed. Cir. 1999). Indeed, it is precisely the argument that this Court rejected in *Xoft*, as discussed in Section I.B.1 above. It is contrary to:

[7] In essence, Plaintiffs' construction would have the claim read "located so as to not be spaced apart from the apparatus volume."

- the explicit definition of "apparatus volume" in claim 1 – "an expandable outer surface defining a three-dimensional apparatus volume" that fills the void left by the removal of the tumor. Ex. 6 ('142 patent), at 8:63-67 (emphasis added);

- the holding and reasoning of this Court's Claim Construction Order in the *Xoft* case – "[Plaintiff's] construction conflates the boundary of the volume with the volume itself . . . ." Ex. 3 (Cl. Constr. Order), at 5;

- Plaintiffs' own arguments in the *Xoft* case – "The film defines the boundary of the volume but the volume is the region of space within that boundary." Ex. 8 (Pl. Cl. Constr. Br.), at 9, 18; and,

- Plaintiffs' construction of the "outer surface" and "apparatus volume" limitations as applied to the Contura on the immediately previous page of their preliminary injunction brief in this case: "The outer surface of the inflatable spherical Contura MLB (an 'expandable outer surface') defines the three-dimensional apparatus volume that fills the resection cavity." Pl. Br. at 17 (emphasis added).

Neither Plaintiffs nor this Court may rewrite the claims. *Process Control Corp.*, 190 F.3d at 1356-57. Every limitation of the claim as written and properly construed must be satisfied for a finding of infringement. *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996). Because the Contura lacks a "radiation source . . . located so as to be spaced apart from the apparatus volume," the Contura does not infringe claim 1, and Plaintiffs cannot show a likelihood of proving otherwise.

3. Claim 1 of the '142 Patent Is Inoperable and Invalid.

For much the same reason that claim 1 is not infringed, it is invalid. Claim 1 requires that the radiation source be "disposed completely within the expandable outer surface," but at the same time that the radiation source be "located so as to be spaced apart from the apparatus volume" defined by the outer surface. Since the radiation source cannot simultaneously be "within" the outer surface and "spaced apart" from the volume defined by that surface, the claim is inoperable and invalid. *See Process Control Corp.*, 190 F.3d at 1359.

By seeking to rewrite the claim, Plaintiffs ask this Court to fix their error. But "[c]ourts may not redraft claims, whether to make them operable or to sustain their validity." *Chef Am. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). Even "a nonsensical result does not require the court to redraft the claims." *Process Control Corp.*, 190 F.3d at 1357; *see also Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1349 (Fed. Cir. 2002) ("Allen argues that one

of skill in the art would understand that the term 'perpendicular' in the claim should be read to mean 'parallel.' Allen stretches the law too far. It is not our function to rewrite claims to preserve their validity. . . ."); *Competitive Techs., Inc. v. Fujitsu Ltd.*, 185 Fed. Appx. 958, 965-66 (Fed. Cir. 2006) ("Because the 'address means' limitation of claim 5 requires ISA structures, and the 'sustain means' limitation of that same claim excludes ISA structures, a person of ordinary skill in the art would be unable to determine the scope of the claims. They are internally inconsistent. . . . [C]laims 5-11 are invalid because of indefiniteness.").

For the reasons stated above, this Court should reject Plaintiffs attempt to redefine "apparatus volume" to mean the "surface" that defines the apparatus volume. *See supra*, Section I.B.1. In *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350 (Fed. Cir. 1999), the Federal Circuit faced a similar issue. As here, the claim explicitly defined a term that, given the term's definition, meant the claim recited an impossibile, nonsensical invention. The Federal Circuit rejected the patentee's request to construe the term in accordance with the specification, or in accordance with "the natural manner in which [the term] make[s] sense." *Id.* at 1356. Instead, the Federal Circuit held that the term as defined in the claim trumped any other evidence allegedly supporting a contrary construction:

> The district court's attempt to use the written description to circumvent the plain language of the claim and the clear definition of the disputed claim language found therein was inappropriate. . . . [W]e do not permit courts to redraft claims. . . . **Where, as here, the claim is susceptible to only one reasonable construction, the canons of claim construction cited by [the patentee] are inapposite, and we must construe the claims based on the patentee's version of the claim as he himself drafted it.**

Process Control, 190 F.3d 1356-57 (emphasis added); *see also Applera Corp. v. Illumina, Inc.*, No. C-07-02845, 2008 WL 501391 at *5 (N.D. Cal. Feb. 21, 2008) (stating, in construing inoperable claim language, that "[w]hile it is tempting to just fix it up in the claim construction process, that temptation would be a dangerous course, for it should be up to the PTO in the first instance to amend claims"). As a result, the claim in *Process Control* was held to recite an impossibility and invalidated on the basis of inoperability. 190 F.3d at 1359 ("[W]hen an

impossible limitation, such as a nonsensical method of operation, is clearly embodied within the claim, the claimed invention must be held invalid.").

Here, as in *Process Control*, the language of claim 1 of the '142 patent explicitly defines the relevant terms and is plainly inoperative on its face.[8] Given its explicit language, claim 1 is invalid for at least two reasons. It is not enabled, *see Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956 (Fed. Cir. 1983) ("Because it is for the invention as claimed that enablement must exist, and because the impossible cannot be enabled, a claim containing a limitation impossible to meet may be held invalid under § 112."), and it is inoperable, *id.*, ("Moreover, when a claim requires a means for accomplishing an unattainable result, the claimed invention must be considered inoperative as claimed and the claim must be held invalid under either § 101 or § 112 of 35 U.S.C."). Accordingly, claim 1 should be held to be invalid, or, at the very least, it should be held a substantial question exists as to its validity.

4. The Contura Does Not Infringe Claim 1 of the '142 Patent as It Lacks a Radiation Source "Disposed Completely Within" the Expandable Outer Surface.

The Contura fails to meet a second limitation of claim 1 because it does not contain a radiation source "disposed completely within" the balloon. Instead, SenoRx uses a radiation source "replaceably disposable within" the balloon, a limitation Hologic explicitly abandoned and disclaimed from claim 1.

a. "Disposed Completely Within" Does Not Mean "Replaceably Disposable Within."

Claim 1, as originally filed, contained the limitation that the radiation source was "replaceably disposable within" the expandable surface of the device. Ex. 9 ('142 Patent

[8] Plaintiffs may state in reply that the prosecution history suggests the inventors meant something different than they actually claimed, *e.g.*, that they meant to claim that the radiation source is "located so as to not be spaced apart from the apparatus volume," or that the radiation source is "disposed completely within and spaced apart from the expandable outer surface" (as claimed in claim 9). However, *Process Control* specifically precludes looking to the prosecution history or other evidence "where, as here, the claim is susceptible to only one reasonable construction." *Id.* at 1357. And the prosecution history is less than clear in any event, simply parroting the language of the claims in some cases, and in others conflating the language of claim 1 and the clearly distinguishable language of claim 9.

Application), at 15. On its face, the plain meaning of "replaceably disposable within" refers to a radiation source that is able to be located in and withdrawn from the balloon (the suffixes "-ably" and "-able" meaning that the radiation source is susceptible to or capable of being both replaced and disposed). During the prosecution of the patent, however, (and after claim 1's rejection over prior art using "replaceably disposable" sources) the word "replaceably" was deleted from the claim limitation, and the limitation amended to read "disposed completely within." There is one conclusion that can be drawn from this – "disposed completely within" does not and cannot mean "replaceably disposable within."

The distinction between these terms is supported by the specification of the '142 patent, which describes two ways in which the radiation source can be loaded into the device:

> The radioactive source 24 can either be **preloaded into the catheter at the time of manufacture**, or **loaded into the device after it has been implanted** into the space formerly occupied by the excised tumor. If loaded after implantation, the solid radiation emitting material 36 can be inserted through lumen 14 on a wire 34, for example using an afterloader (not shown).

Ex. 6 ('142 patent), at 5:5-11 (emphasis added). That is, according to the specification, a radiation source may be "replaceably disposable" in the device, *i.e.*, sometimes within the device and sometimes not *(e.g.*, when the device is used with an afterloader). Or, alternatively, the radiation source may be "preloaded into the catheter at the time of manufacture," *i.e.*, invariably located within the expandable outer surface, and thus "disposed completely within."

This distinction is further supported by the prosecution history. As set forth above, claim 1 initially recited the "replaceably disposable within" limitation. Ex. 9 ('142 Patent Application), at 15. However, this soon changed. On October 31, 2001, the United States Patent & Trademark Office ("PTO") rejected claim 1 as anticipated over U.S. Patent No. 6,036,631 to McGrath ("McGrath"), citing in particular Fig 2B. *See* Ex. 10 ('142 Patent Office Action), at 2. Figure 2B of McGrath depicts a device with an insertable radiation source, consisting of radioactive seeds, located within a lumen in a catheter. McGrath states that the radiation source may be "implemented in such a manner that the seeds are movable along the axial length of probe 28b within energy delivery lumen 34." Ex. 11 (McGrath), at Fig. 2B & col. 5:32-40.

In response, on March 11, 2002, the Hologic inventors amended claim 1 to delete the requirement that the source be "replaceably" disposable in the balloon. Ex. 12 ('142 Patent Response to Office Action), at 11. The inventors explained McGrath is different from claim 1, as amended, because of a "number of key differences in structure," including that claim 1's "radiation source is disposed completely within the expandable surface." *Id.* at 6. The inventors continued:

> The device of McGrath is not configured for use interstitially, it is configured for use interluminally, with balloons provided only to hold its catheter within a lumen, or to dilate a lumen. Accordingly, **the radiation source in McGrath is not located completely within any of the disclosed balloons** . . . . **Rather, McGrath provides an x-ray tube that slides within a catheter, or a plurality of radiation-emitting seeds 52 'essentially forming a linear source.'**

Id. at 7 (emphasis added).[9] That is, to avoid prior art encompassing an insertable radiation source, the inventors modified claim 1 to require that the radiation source invariably be located within the balloon (as opposed to "replaceably" located in it). In view of the claim language, patent specification and prosecution history, claim 1 clearly excludes "replaceably disposable" radiation sources.

b. The Contura Is Used with a "Replaceably Disposable" Radiation Source and Lacks a Radiation Source "Disposed Completely Within" the Outer Surface.

The radiation source used with the Contura is not preloaded in the balloon. *See* Arthur Decl. ¶ 25. Instead, it is delivered by way of an afterloader at the time of treatment. The afterloader inserts the radiation source into the Contura's lumens to preprogrammed positions, for predetermined periods of time, before being withdrawn back into the afterloader. *Id.* This sequence of events – the placement and withdrawal of the radiation source into the Contura balloon – occurs for each "fraction" of the treatment received by the patient, and also usually is repeated several times during each fraction. This constitutes precisely the "replaceably

[9] The same distinctions, and essentially the same arguments, were made with respect to other balloon catheter prior art that the Examiner had cited for obviousness. Ex. 12 ('142 Patent Response to Office Action), at 8-9.

disposable" method of radiation insertion that Plaintiffs struck from claim 1 in the face of the prior art in favor of a limitation specifying a radiation source located "completely within" the device. Accordingly, the Contura does not infringe claim 1.

5. Claim 1 of the '142 Patent Is Rendered Invalid by the Prior Art.

If Plaintiffs' flawed claim interpretation of "apparatus volume" is accepted, claim 1 of the '142 patent suffers another flaw – it is anticipated by, or obvious over, the prior art. United States Patent No. 5,931,774 to Williams (the "'774 patent") is one such reference. *See* Ex. 13 ('774 patent). As seen from Figure 3 of the '774 patent, and as discussed in detail in the Declaration of Dr. Colin Orton (¶¶ 30-50), the patent discloses a balloon catheter, including an asymmetrically-placed radiation source (consisting of an inner balloon (40) filled with radioactive treatment fluid (42)) within the outer balloon (24):

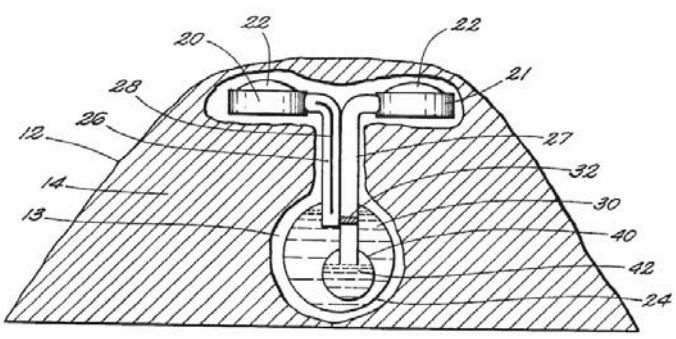


FIG. 3

Figure 3 and the corresponding disclosure of the '774 patent anticipate every element of claim 1, as set forth in the chart below:

Claim 1	United States Patent No. 5,931,774 (Williams, 1999)
1. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:	The '774 patent describes an apparatus for interstitial brachytherapy for treating target tissue surrounding a surgical extraction. Ex. 13 ('774 patent), at Fig. 3 & col. 2:1-3, 3:6-10, 3:22-28; Orton Decl. ¶¶ 30-34, 43-44.
an expandable outer surface defining a three-dimensional apparatus	The device of the '774 patent consists of an expandable

Claim 1	United States Patent No. 5,931,774 (Williams, 1999)
volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;	balloon defining a volume configured to fill the interstitial void created by the extraction of diseased tissue and defining the inner boundary of target tissue being treated. Ex. 13 ('774 patent), at Fig. 3 & col. 7:41-60, 8:54-59; Orton Decl. ¶¶ 35-37, 44-45.
a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume,	Applying (without agreeing to) Plaintiffs' constructions, the device of the '774 patent has a radiation source disposed completely within the balloon, and spaced apart from the surface of the balloon. Ex. 13 ('774 patent), at Fig. 3 & col. 8:35-63; Orton Decl. ¶¶ 36, 40-42, 46.
the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.	The radiation source of the '774 patent is asymmetrically located and arranged within the balloon. Ex. 13 ('774 patent), at Fig. 3; Orton Decl. ¶¶ 47-50. This provides predetermined asymmetric isodose curves with respect to the apparatus volume. Orton Decl. ¶¶ 47-50.

* * *

In sum, Plaintiffs cannot show they likely will succeed in proving claim 1 of the '142 patent is infringed and valid. The claim is not infringed by the Contura, for at least the reason that the Contura lacks a "radiation source . . . located so as to be spaced apart from the apparatus volume." It also is not infringed because the Contura utilizes a "replaceably disposable" radiation source, not one located completely within the balloon. Alternatively, claim 1 is inoperable, or anticipated by (and obvious over) the '774 patent.

II. THE REMAINING FACTORS ALL SUPPORT DENIAL OF AN INJUNCTION.

The availability of the Contura on the market clearly serves the public interest by allowing treatment of patients requiring balloon brachytherapy that the MammoSite cannot treat.

Thus, Plaintiffs' efforts to link the Contura to harm to the balloon brachytherapy marketplace fail. There is no harm to Plaintiffs that could not be compensated by monetary damages if necessary, nor can Plaintiffs show that the balance of harms tips in their favor.

A. An Injunction Is Contrary to the Public Interest.

The Contura allows physicians to offer the advantages of balloon brachytherapy in connection with breast conserving surgery to many women who cannot be treated by the MammoSite. And, even for patients for whom the MammoSite could be an option, the Contura allows physicians in a number of cases to offer better treatment. The reason is simple – balloon brachytherapy depends on accurate placement of the radiation dose. The Contura's multi-lumen design allows tremendous flexibility in the placement of that dose as compared to the single-lumen MammoSite. The Contura is simply the next generation device in balloon brachytherapy. It solves the weaknesses of the MammoSite while maintaining the strengths of balloon brachytherapy.

1. The Contura Enables Critical Cancer Treatment for Women Otherwise Not Treatable by Balloon Brachytherapy.

A primary limiting factor in the use of balloon brachytherapy is the need to limit the dose of radiation to critical and highly radiation sensitive areas such as the skin, ribs, heart and lungs, while still meeting the target goals of irradiating the area of tissue in which tumor recurrence is most likely. *See* Arthur Decl. ¶¶ 23, 30; Israel Decl. ¶¶ 17-19. In single-lumen devices such as the MammoSite, physicians have a limited ability to shape the dose of radiation. Thus, if a patient's tumor is located too near her chest wall and ribs, or too near her skin, as is often the case for women with relatively small breasts, treatment with the MammoSite device would not be undertaken. *See* Arthur Decl. ¶ 30; Israel Decl. ¶¶ 22-23, 32.

In contrast, the multi-lumen design of the Contura allows a great degree of flexibility in prescribing and delivering a three-dimensional radiation dose to a woman's breast. *See* Arthur Decl. ¶¶ 31-32; Israel Decl. ¶¶ 21-25, 27. Radiation oncologists and physicists using the Contura are able to deliver a highly specific, targeted and contoured dose profile that limits radiation overexposure of critical tissue while ensuring that the target tissue receives an appropriate dose.

See Arthur Decl. ¶¶ 31-33; Israel Decl. ¶¶ 21-25, 27. Although estimates of how many more women are treatable with the Contura vary, they all make clear that there is a significant number of women who will benefit from the availability of the Contura. For example, one renowned breast surgeon who has worked extensively with the MammoSite and the Contura believes that the Contura's design will allow the device to treat between 20% and 30% more women than the MammoSite. *See* Israel Decl. ¶ 33; *see also* Arthur Decl. ¶ 33. Similarly, a multi-institutional clinical study (currently undergoing Investigational Review Board review) designed to scientifically compare the results of single-lumen versus multi-lumen treatment hypothesizes that the multi-lumen design will result in the ability to improve dosimetry in a minimum of 15% of patients. *See* Arthur Decl. ¶ 36. Dr. Arthur believes the results likely will be higher, showing an ability to improve dosimetry in 20% or more of patients. *Id.*

The ability of the Contura to treat more women than the MammoSite makes this a particularly inappropriate case for preliminary injunctive relief. *See Hybritech, Inc. v. Abbott Labs*., No. CV 86-7461, 1987 WL 123997, *1015 (C.D. Cal. July 14, 1987), *aff'd* 849 F.2d 1446 (Fed. Cir. 1988) (despite the fact that the patentee had shown a likelihood of success on the merits and irreparable harm, an injunction should not issue because there was a "critical public interest" in having the infringing cancer and hepatitis testing kits available); *Datascope Corp. v. Kontron, Inc*., 611 F. Supp. 889, 895 (D. Mass. 1985), *aff'd* 786 F.2d 398 (Fed. Cir. 1986) (refusing to enjoin the production of the pacemaker leads at issue, citing some physicians' preference for the infringing leads over others on the market). Removing the Contura from the market clearly would harm the public interest. *See* Arthur Decl. ¶ 43 ("It is my opinion that an injunction removing the Contura from the market would negatively impact the care of patients, negatively impact present scientific investigation and progress towards improved APBI treatment delivery, and impede investigation into the benefits of balloon brachytherapy in general, and multi-lumen balloon brachytherapy in particular.").

2. The Contura Is Safe and Effective.

Plaintiffs claim that there is a lack of clinical data demonstrating the safety of the Contura, implying that the lack of clinical studies means that the Contura is unsafe. Pl. Br. at 23.

That argument overlooks several critical facts. First, by approving the Contura for marketing in view of the MammoSite as a "predicate device," the FDA has determined that the Contura is at least "as safe and effective" as the MammoSite. *See* 21 U.S.C. § 360c(i)(1); 21 C.F.R. § 807.100(b); *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 264 F.3d 344, 360 & n.13 (3d Cir. 2001).[10]

Second, physicians have used, and continue to use, the Contura successfully. [redacted] Indeed, the feedback from practicing physicians has been overwhelmingly positive. Arthur Decl. ¶¶ 31-37, 42; Israel Decl. ¶¶ 25, 29, 33-34. This stands in stark contrast to the limited patient data available for the MammoSite when it was first introduced into the market. Ex. 15 (MammoSite Instruction Manual), at 9 (reporting data for 43 patients in MammoSite pre-marketing clinical trial).

Third, SenoRx has initiated a master "Registry Study," designed to track the efficacy and safety of the Contura in 342 patients over a five-year period. Ex. 16 (Contura Registry Study Protocol), at 5. Plaintiffs followed a similar post-approval testing regimen after the MammoSite obtained 510(k) approval from the FDA. SenoRx has enrolled large and well-respected medical centers and industry leaders for purposes of the study. Gearhart Decl. ¶ 19. The principal investigators of this study include Douglas Arthur, M.D., Frank Vicini, M.D., and Dorin Todor, Ph.D., three of the most prominent and well-respected figures in the field of breast brachytherapy. *Id.*; [redacted]

---

[10] [redacted]

[redacted] The Contura is at least as safe as, if not safer than, the MammoSite.

B. Plaintiffs Will Not Suffer Irreparable Harm.

A showing of irreparable harm is "[c]entral to the movant's burden." *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996). Plaintiffs must provide a "clear showing" they will suffer irreparable harm in the absence of injunctive relief – a nearly impossible task in this case, where Plaintiffs have admitted the adequacy of a monetary remedy by their grant of a license on the same patents to one of their (and SenoRx's) competitors. *See Nutrition 21 v. United States*, 930 F.2d 867, 870-71 (Fed. Cir. 1991); *Reiffin v. Microsoft Corp.*, 158 F. Supp. 2d 1016, 1028 (N.D. Cal. 2001) ("[E]vidence that a patentee is willing to forgo his patent rights for compensation militates against a finding of irreparable harm.").

Plaintiffs assert that irreparable harm is to be presumed after a showing of likelihood of success on the merits. Pl. Br. at 19. But, contrary to Plaintiffs' assertion, the majority of courts that have considered the issue have reached precisely the opposite conclusion.[11] Further, even those cases Plaintiffs cite as support require, at the very least, a "strong" showing of likelihood of success prior to any presumption, which Plaintiffs here lack. *See, e.g., Docusign, Inc. v. Sertifi, Inc.*, 468 F. Supp. 2d 1305, 1309 (W.D. Wash. 2006) ("Docusign has not made a strong showing of likely success on the merits and is therefore not entitled to a presumption of irreparable harm."). Nonetheless, regardless of the standard imposed, Plaintiffs cannot establish irreparable harm.

[11] *See, e.g., Tiber Labs., LLC v. Hawthorn Pharm., Inc.*, 527 F. Supp. 2d 1373, 1380 (N.D. Ga. 2007) ("This Court agrees that eBay does not leave room for a presumption of irreparable injury in patent cases, whether raised at the preliminary or permanent injunction phase."); *Voile Mfg. Corp. v. Louis Dandurand et al.*, No. 07-CV-396 TC, slip op. at pp. 6-8 (D. Utah March 14, 2008); *Sun Optics, Inc. v. FGX Int'l, Inc.*, No. Civ-07-137, 2007 WL 2228569, at *1 (D. Del. Aug. 2, 2007) (same); *Torspo Hockey Int'l, Inc. v. Kor Hockey Ltd.*, 491 F. Supp. 2d 871, 881 (D. Minn. 2007) (same); *Chamberlain Group, Inc. v. Lear Corp.*, No. 05-C-3449, 2007 WL 1017751, at *5 (N.D. Ill. Mar. 30, 2007) (same); *z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437, 440 (E.D. Tex. 2006) (same).

1. Plaintiffs' Own Actions Show There Is No Irreparable Harm.

a. Plaintiffs' Delay in Seeking Injunctive Relief Undermines Their Claim of Urgency.

Plaintiffs' arguments regarding irreparable harm are based on the notion that the Contura must be removed from the market now, before the merits of the case are fully aired at trial. However, Plaintiffs' delay in filing this suit and seeking injunctive relief undermines that argument and "negat[es] the idea of irreparability." *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 974 (Fed. Cir. 1996); *see also High Tech Med. Instr., Inc. v. New Image Indus., Inc*., 49 F.3d 1551, 1557 (Fed. Cir. 1995) ("[D]elay in seeking a remedy is an important factor bearing on the need for a preliminary injunction.").

[redacted] If the harm resulting from the Contura's introduction to the market really were "irreparable," Plaintiffs would have sought to enjoin SenoRx before the product's full commercial launch, rather than waiting months to take action. Plaintiffs' willingness to wait "militates against the issuance of a preliminary injunction by demonstrating that there is no apparent urgency to the request for injunctive relief." *High Tech Med. Instr*., 49 F.3d at 1557.

b. Plaintiffs' Willingness To License a Competitor Under the Patents-In-Suit Shows There Is No Irreparable Harm.

Plaintiffs' willingness to license a competitor's alleged infringement of the patents-in-suit demonstrates that money damages are sufficient to compensate Plaintiffs for the patent rights at issue in this case. "[A]s the Federal Circuit has recognized, a patentee's willingness to 'forgo its patent rights for compensation' by offering to license its patent further militates against the

existence of irreparable harm." *Tiber Labs.*, 527 F. Supp. 2d at 1382 (quoting *High Tech Med. Instr., Inc.*, 49 F.3d at 1557); *Reiffin*, 158 F. Supp. 2d at 1028 ("[E]vidence that a patentee is willing to forego his patent rights for compensation militates against a finding of irreparable harm.").

[redacted]

Thus, far from establishing that monetary damages are insufficient compensation for allegedly infringing the patents-in-suit, Plaintiffs have proven monetary damages are a sufficient remedy for the exact wrong alleged in this case. *See* Weinstein Decl. ¶ 33; *3M Unitek Corp. v. Ormco Co.*, 96 F. Supp. 2d 1042, 1051 (C.D. Cal. 2000) ("The plaintiff must affirmatively demonstrate that money damages will be inadequate" in a patent infringement case.).

[redacted]

12 [redacted]

2. The Contura Will Expand, Not Harm, the Market.

Plaintiffs claim that "SenoRx's infringing presence in the market damages the reputation of APBI as an effective treatment modality," and deny that the Contura will treat patients the MammoSite cannot. Pl. Br. at 23 ("There is no basis, therefore, for SenoRx's assertion that the Contura MLB can treat a different patient population than the MammoSite."). For support, Plaintiffs cite only the self-serving declaration of Hologic's Senior Director of Product Marketing, Mr. Magnuson. *Id.* That declaration plainly is insufficient to justify the extraordinary relief Plaintiffs seek.

Plaintiffs' allegations that the Contura will harm the reputation of balloon brachytherapy are entirely speculative[13] and contradicted by the sworn declarations of Dr. Arthur and Dr. Israel, experienced physicians and opinion leaders in the field. Arthur Decl. ¶ 42; Israel Decl. ¶¶ 26-34. Likewise, SenoRx has shown the Contura can treat a broader patient population. *See supra*, Section II.A.1.

[redacted]

[13] Such speculation is not the proper basis for establishing the need for preliminary injunctive relief. *See Visto Corp. v. Sproqit Technologies, Inc.*, 413 F. Supp. 2d 1073, 1093 (N.D. Cal. 2006) (declining to issue preliminary injunction in part because "[t]he harms Visto points to in order to establish irreparable harm appear more theoretical or potential than actual or proven at this point"); *Atari Corp. v. Sega of Am., Inc.*, 869 F. Supp. 783, 792 (N.D. Cal. 1994) (declining to issue preliminary injunction where movant's "showing [was] too speculative to support a finding of the likelihood of irreparable harm").

3. Plaintiffs' "Concerns" About Off-Label Promotion Do Not Justify the Injunction They Seek.

Plaintiffs claim they are irreparably harmed because of a "concern" that SenoRx is promoting the Contura in a manner "inconsistent with the FDA-approved labeling." Pl. Br. at 23.[14] They state such harm justifies the removal of the Contura from the marketplace and preclusion of all sales and commercial uses of the device. Plaintiffs' argument is without merit.

---

[14] Contrary to what the Plaintiffs argue in their motion, the Contura and MammoSite labels are not identical. The MammoSite's label warns that the device should not be implanted unless imaging "verifies a minimum distance of 5 mm from balloon surface to skin surface; however, a minimum distance of 7 mm from balloon surface to skin surface is recommended." Ex. 15 (MammoSite Instruction Manual), at 5 (emphasis added). The MammoSite label also contraindicates the delivery of radiation if the minimum distance is less than 5 mm. *Id.* The Contura's FDA-approved label is not as restrictive. It warns not to implant the device "if a skin

(continued...)

First, it is SenoRx's policy not to promote off-label, and SenoRx has taken steps to ensure its sales force complies with that policy. *See* Gearhart Decl. ¶ 15. Consequently, there is no basis for Plaintiffs' presumption that, if the Contura remains on the market, SenoRx is or will be promoting it for off-label uses. *See, e.g., City of Los Angeles v. Lyons*, 461 U.S. 95 (1983) (injunctive relief inappropriate where little likelihood future conduct would result in irreparable harm).

Second, Plaintiffs' alleged risk of harm from off-label promotion is overstated and does not justify Plaintiffs' request to have the Contura removed from the marketplace. The FDA has given SenoRx clearance to market the Contura for all "on-label" indications. Once the Contura has been sold, physicians are permitted to use the Contura for both "on-label" and "off label" uses. Indeed, the FDA permits SenoRx to provide information concerning off-label uses at the request of physicians. *See* 21 U.S.C.A. § 360aaa-6. Moreover, 21 U.S.C. § 396 makes this clear: "Nothing in this chapter shall be construed to limit or interfere with the authority of a healthcare practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease . . . ." 21 U.S.C. § 396 (emphasis added). The unstated assumption that physicians actually will use the device in such a manner as to harm patients – a predicate to Plaintiffs' irreparable harm argument – is completely unwarranted. *See, e.g.*, Arthur Decl. ¶¶ 38-41. As the Supreme Court has explained, "'off-label' usage of medical devices is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (citations omitted). Plaintiffs' "off-label" claims provide no basis for their request to enjoin the lawful marketing and use of the Contura. *See, e.g., Riles v. Shell Exploration and Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002) (an injunction cannot impose unnecessary restraints on lawful activity); *Gemveto Jewelry Co. v. Jeff Cooper Inc.*, 800 F.2d 256, 259 (Fed.

(...continued from previous page)
surface to balloon surface distance of less than 5 mm will result." Ex. 27 (Contura Instructions for Use), at 2 (emphasis added). And, as opposed to the MammoSite label, the Contura label contains no contraindication regarding the delivery of radiation for a skin surface to balloon surface of less than 5 mm. *Id.*

Cir. 1986) (same); *Natural Res. Def. Council, Inc. v. Winter*, 508 F.3d 885, 886 (9th Cir. 2007) ("Injunctive relief must be tailored to remedy the specific harm alleged, and an overbroad preliminary injunction is an abuse of discretion."); *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 941 F.2d 970, 974 (9th Cir. 1991) (same); *Riles*, 298 F.3d at 1311 (court must "narrowly tailor an injunction to fit the specific adjudged violations").

Finally, Plaintiffs are not the arbiters of what constitutes off-label promotion. And, a preliminary injunction hearing for patent infringement is not the proper forum to litigate that issue. Indeed, Plaintiffs have no private right of action to enforce FDA regulations and cannot use a preliminary injunction hearing to create such a right. "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

4. The Economic Harm Alleged by Plaintiffs Is Not Irreparable.

The touchstone of irreparable harm is the inadequacy of monetary damages to compensate a plaintiff for his injury. *See eBay*, 547 U.S. at 391; *Nelson v. Nat'l Aeronautics & Space Admin.*, 512 F.3d 1134, 1146 (9th Cir. 2008); *Nutrition 21*, 930 F.2d at 871; *RasterOps v. Radius, Inc.*, 861 F. Supp. 1479, 1496 (N.D. Cal. 1994). Nevertheless, Plaintiffs contend that harms that by definition are monetarily compensable are "irreparable" and support injunctive relief. Plaintiffs' arguments are without merit.

Any economic damage to Plaintiffs in the form of lost sales, lost market share, or price erosion can be observed, measured and quantified as economic damages. Declaration of Roy Weinstein ("Weinstein Decl."), at ¶¶ 21-23. Both parties closely track sales and expense data for their products and these data are sufficient to estimate any economic damage resulting from Contura sales during the pendency of the litigation, for which Plaintiffs can be compensated if need be. *Id.*

First, SenoRx is not judgment-proof. [redacted]

Second, [redacted] This argument makes no sense. Clearly by the time the Court has rendered a final judgment in this matter, there will be ample Contura sales data from which to make an award of money damages.

Third, the APBI market is not "nascent" or "high-growth" such that a temporary loss of market share or sales is irreparable. Weinstein Decl. ¶¶ 28-29. Plaintiffs' product has been available since 2002, and for the last several years, Plaintiffs have failed significantly to penetrate the potential market for post-lumpectomy radiation. Gearhart Decl. ¶ 14; Weinstein Decl. ¶ 28. The cases cited in Plaintiffs' brief are inapposite. *See* Pl. Br. at 21. Both *800 Adept, Inc. v. Murex Secs., Ltd.*, No. 6:02-cv-1354, 2007 WL 1101238 (M.D. Fla. Apr. 12, 2007), and *TiVo, Inc. v. Echostar Communicators Corp.*, 446 F. Supp. 2d 664 (E.D. Tex. 2006), analyze the issuance of a permanent injunction after a trial on the merits and verdict in favor of the patentee. Additionally, in *TiVo*, the court emphasized the risk of lasting market share loss to the patentee because its customers tended to remain loyal to the company from which they obtained their first product. *Tivo*, 446 F. Supp. 2d at 670. Here, Plaintiffs have made no such showing. Nor could they. Health care professionals can easily switch between the MammoSite and Contura. *See* Gearhart Decl. ¶ 14.

Fourth, equally groundless are Plaintiffs' claims of price erosion. The Contura and the MammoSite have the same price, $2750, [redacted]

---

[15] [redacted]

Fifth, Plaintiffs' assertion that they will be unable to fund continued research and development for the MammoSite if its sales and profits decrease is simply not credible. Plaintiffs generated over $371.4 million in revenue in the most recent quarter alone. Weinstein Decl. ¶ 17. MammoSite sales accounted for no more than 3% of this revenue. *Id.* ¶ 37. Certainly, Plaintiffs have the ability to continue research and development even if sales and profits of MammoSite decrease. *Id.* ¶¶ 37-38.

Finally, [redacted] *See Biagro Western Sales, Inc. v. Helena Chem. Co.*, 160 F. Supp. 2d 1112, 1135 (E.D. Cal. 2001) (direct competition does not *per se* constitute irreparable harm). As discussed *supra*, any decrease in MammoSite sales, market share or price as a result of SenoRx's direct competition in the APBI market is measurable and quantifiable as monetary damages. Weinstein Decl. ¶¶ 21-23.

5. Plaintiffs' Reputation as an Innovator Will Not Be Harmed if an Injunction Does Not Issue.

Plaintiffs' argument regarding their reputation as an innovator, and the effect that this lawsuit will have on competitors North American Scientific Inc. and Cianna Medical, is speculative. *See Al-Site Corp. v. Cable Care Sunglasses*, 911 F. Supp. 410, 417 (N.D. Cal. 1994) ("Plaintiff's argument that Defendant's alleged infringement will encourage others to infringe is speculative and unconvincing."). The Plaintiffs seem to be suggesting that the only way they can protect that reputation is by "send[ing] a message" to those competitors that they will be able to enforce their patent rights. Pl. Br. at 22. [redacted] Thus, even if SenoRx is infringing the Plaintiffs' patents (which it is not), it is unclear how the result in this case would have any effect on the actions of those other companies.

[redacted]

Moreover, Plaintiffs' argument is undermined by their significant investment in one of the companies to whom they ask this Court to send a message – Cianna Medical. Hologic's most recent 10-Q lists a $1 million dollar investment in Cianna, [redacted]. Ex. 29 (Hologic's 2/12/2008 10-Q), at 12; [redacted]

C. The Balance of Harms Favors SenoRx.

Finally, the alleged harm to Plaintiffs in allowing the Contura to remain on the market pending trial is far outweighed by the harm to SenoRx of removing the Contura from the market.

First, [redacted]

Second, [redacted]

Third, [redacted]

Fourth,

Plaintiffs' total revenue for the most recent quarter alone exceeded $371.4 million. *Id.* ¶ 17. Moreover, the majority of Plaintiffs' business is unrelated to the MammoSite, which accounted for just 3% of Hologic's revenue last quarter. *Id.* ¶ 37.

Plaintiffs have advanced no proof of any specific, measurable harm they will suffer as a result of the Contura's availability through the end of trial.[16] *See Visto Corp. v. Sproqit Techs., Inc.*, 413 F. Supp. 1073, 1093 (N.D. Cal. 2006) (denying preliminary injunction where the harms to plaintiff "appear more theoretical or potential than actual or proven at this point" whereas

[16] Plaintiffs offer only one basis for finding the balance of harm tips in their favor – the maxim that infringers "who have apparently decided to expand their business based on infringing activities cannot complain that the entry of an injunction to enforce the patent laws will harm that business." Pl. Br. at 24. But that principle "is limited to a permanent injunction issued after trial and is not 'remotely related to a potential destruction of [an alleged infringer] without its day in court.'" *Atari Corp. v. Sega of Am., Inc.*, 869 F. Supp. 783, 792 (N.D. Cal. 1994) (citing *Illinois Tool Works Inc. v. Grip-Pak Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990)) (emphasis added); *see also Al-Site Corp.*, 911 F. Supp. at 418 (same).

"neither parties appear to dispute that issuance of the preliminary injunction would devastate [defendant's] business"). As such, Plaintiffs have failed to meet their burden to demonstrate the balance of harm tips in their favor.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' request for a preliminary injunction should be denied.

Dated: March 28, 2008

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

By: s/F.T. Alexandra Mahaney
F.T. Alexandra Mahaney
amahaney@wsgr.com

Attorneys for Defendant and Counterclaimant
SENORX, INC.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On March 28, 2008, I served a copy(ies) of the following document(s):

DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION [REDACTED VERSION]

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on March 28, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Counterdefendants.

Case No. 08-CV-0133 RMW

DECLARATION OF DOUGLAS ARTHUR, M.D. IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Date: April 21, 2008
Time: 2:00 p.m.
Courtroom: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

I, Douglas Arthur, M.D., declare that:

BACKGROUND

1. The facts set forth below in this declaration are based on my personal knowledge, and if called as a witness, I could and would testify competently to those facts.

2. I am a Professor of Radiation Oncology and Vice-Chairman of the Department of Radiation Oncology at the Virginia Commonwealth University – Medical College of Virginia, Massey Cancer Center. I also am the Associate Director of Clinical Affairs at the Massey Cancer Center.

3. My complete educational and employment background are described in my C.V., which is attached hereto as Exhibit 1. In summary, I received my B.S. degree in Biology, with a minor in physics, from Dickinson College in 1985. I subsequently graduated from the Bowman Gray School of Medicine at Wake Forest University, followed by a transitional internship at the Roanoke Memorial Hospital in Roanoke, Virginia and a four-year residency in Radiation Oncology at the Medical College of Virginia Hospitals, Virginia Commonwealth University in Richmond. I then completed a one month brachytherapy fellowship at Memorial Sloan Kettering Cancer Center, following which I returned to accept a position at VCU, where I remain to this date.

4. I currently practice medicine at VCU in connection with, and in addition to, my teaching and research responsibilities. My medical practice and clinical research are focused on breast cancer and accelerated partial breast irradiation ("APBI"), including balloon brachytherapy.

5. I am involved with numerous organizations that are involved with the APBI medical community, including the American Brachytherapy Society ("ABS"), which I have served as Chairman of the Board and President. I currently am the program chairman for the ABS Breast Brachytherapy School, and have managed this teaching program since 2005. I also am an active member and involved with the American Society for Therapeutic Radiation and Oncology.

6. I am a co-Principal Investigator of the ongoing National Cancer Institute-sponsored phase III clinical trial comparing whole breast irradiation with partial breast irradiation, sponsored by the National Surgical Adjuvant Breast and Bowel Project / Radiation Therapy Oncology Group (the "NSABP/RTOG phase III study"). I also was a participating investigator of: the original FDA trial and DCIS trial of the MammoSite device; the multicatheter breast brachytherapy trial RTOG 9517; and the 3D conformal external beam partial breast irradiation trial RTOG 0319.

7. I am one of the principle investigators for the proposed SenoRx clinical study regarding the Contura. I am compensated $2,000 / month for management of that study. I also currently serve as a consultant for SenoRx, and receive $36,000 per year in that role.

8. I have never been a formal consultant for any of the Plaintiffs in this case, but I did work closely with Proxima with respect to the MammoSite devices from their beginning, including assisting in the development and teaching of the original Proxima courses introducing the MammoSite device to the medical community. I also have been invited to participate, and have participated, in numerous lectures sponsored by the Plaintiffs' over the years.

9. I also serve on the board of advisors for companies named Calypso and Advanced Radiation Therapy, and am one of many several representatives (unpaid) of the ABS on Xoft's Protocol Advisory Board.

10. In my practice, I personally have implanted over 70 MammoSite balloons, and have treated at least 130 patients in whom the MammoSite devices have been implanted.

11. Although the Contura is relatively new to the market, I have placed between 10-15 Contura devices to-date and treated close to twice that number of patients in whom the Contura was implanted.

12. I have not testified as an expert in any case during the last four years.

13. I am being compensated for my time in this matter at my usual rate of $500 per hour. My compensation does not depend on the outcome of this litigation.

APBI GENERALLY

14. Not every woman who is to be treated for breast cancer is a candidate for breast conservation therapy and not every women eligible for breast conservation therapy is elgible for APBI. APBI is only indicated for a select group of patients where the risk of tumor recurrence is believed to be only in the area of the resected tumor cavity.

15. The goal of any radiation treatment is to delivery sufficient dose to the target while avoiding excessive dose to adjacent normal tissue. The treatment goal of APBI is no different and specifically is to irradiate the tissue immediately surrounding the tumor cavity (this defined target is the area that most likely harbors residual microscopic malignant cells) while minimizing damage to healthy tissue.

16. The efficacy of an APBI treatment regimen is directly related to the treatment's ability to target the tissue that needs treatment with an appropriate radiation dose, whereas the toxicity (safety) of an APBI treatment regimen is directly related to the treatment's ability to reduce (as much as possible) the radiation dose received by normal breast tissue and other adjacent structures such as the skin, ribs and lungs. It is the appropriate balance of sufficient dose to the target and satisfactorily reduced dose to the adjacent normal tissues that the radiation oncologist struggles with on a case by case basis.

17. There currently are three commonly used methods of APBI: 1) the multicatheter brachytherapy approach (using multiple catheters inserted into the breast); 2) the 3D conformal external beam approach; and 3) balloon based brachytherapy. These three methods of APBI delivery are included in the NSABP/RTOG phase III study. Although, the trial is not designed to directly inter-compare these methods of treatment, safety and effectiveness of these three methods as a group will be evaluated in relation to whole breast irradiation.

18. The multicatheter approach, by virtue of unlimited catheter placement, allows precise tailoring of the radiation dose delivery allowing patient specific individualization. However, this approach has disadvantages that include increased trauma to the breast tissue as a result of catheter placement and the associated highly operator dependence (e.g., in placing the catheters).

19. The 3D conformal external beam treatment approach is an advanced form of external beam radiation (like that used in whole breast irridiation). By using multiple targeted beams of radiation, 3D conformal beam seeks to limit the amount of tissue that is irradiated. This approach is non-invasive, and the dose delivered in this way is more homogenous then with any brachytherapy, therefore, promising improved cosmetic outcome. However, to date there is limited data published on its use and questions remain regarding the large amount of breast tissue that gets included in the prescription isodose line as well as whether methods have been appropriately developed to compensate for the potentially negative effects of breathing motion and patient set up error.

20. Balloon based brachytherapy presents a treatment approach that, although invasive, is less traumatic to the breast then as seen with the multicatheter approach and maintains a limited volume of treated breast tissue while avoiding the patient set-up and breathing motion questions of 3D-conformal external beam approach. However, balloon based brachytherapy, as presently practiced with the MammoSite balloon, also has disadvantages relative to the other methods of treatment, including a very limited ability to tailor the dose and the fact that the safety and effectiveness of MammoSite based treatment is highly reliant on the size, shape and location of the surgical cavity created by resection of the tumor.

BALLOON BRACHYTHERAPY GENERALLY

21. Balloon based brachytherapy, in general, involves the following steps. After a potentially eligible patient is identified and a lumpectomy completed with confirmed negative surgical margins, the cavity is then evaluated for balloon catheter placement. Although placement at the time of lumpectomy is possible, evidence suggests that a reduction in complications is seen when placed during a subsequent separate procedure. Once the balloon catheter device is inserted into a lumpectomy cavity (in most cases by the breast cancer surgeon), the intra-cavitary balloon is inflated with sterile water or saline mixed with a contrast agent.

22. The breast, with balloon catheter in place, is then imaged by CT scan and appropriateness for treatment judged based on the general 'fit' of the balloon within the catheter and the ability to meet conformance, symmetry and skin spacing criteria. Once appropriateness

for treatment is determined, 3D based dosimetric treatment planning follows and confirmation of compliance with dosimetric goals completed and treatment initiated.

23. Both a radiation oncologist and radiation physicist are involved in the dose planning and plan evaluation and approval process. As previously stated, the goal of dose planning is to ensure that the target tissue receives the prescribed dose, while minimizing the dose to surrounding normal tissue. The dose to be received by the normal breast tissue immediately adjacent to the balloon surface, skin and ribs are specifically evaluated to reduce toxicity.

24. The radiation dose delivered to any particular volume of tissue is primarily dependant on the strength of the radioactive source, distance between the radiation source and the tissue, and the time the tissue is exposed to the radiation source at that distance. Accordingly, the radiation plan typically incorporates specified "dwell positions," *i.e.*, the location along the catheter at which the radiation source is paused. The specific location and time length of each dwell position used collectively determines the ultimate dosimetric pattern of dose delivered.

25. Once a treatment plan is approved, treatment is initiated. Presently, APBI is most commonly delivered twice a day, six hours in between each treatment, over a five day period for a total of ten treatments. For each treatment, the patient travels to a hospital or other treatment center where a radiation "high dose rate remote afterloader" is located. A remote afterloader is a computerized machine that contains a highly radioactive radiation source attached to the end of a robotically controlled wire. The afterloader is connected to the balloon catheter, and the radiation source is robotically inserted into the balloon catheter in accordance with the radiation dose plan, withdrawing the source back into the machine when finished.

26. The mostly commonly accepted dose delivery scheme for APBI treatment is presently 34 Gray ("Gy") delivered twice a day over 5 days for a total of 10 individual treatments.

THE HOLOGIC MAMMOSITE

27. There are several MammoSite balloon catheters available on the market – two spherical balloons of different sizes, and an ellipsoidal balloon. The MammoSite catheters have only a single central lumen into which a radioactive source is inserted. The two spherical MammoSites are recommended for use with a single dwell position located in the center of the balloon, although it is recognized that multiple dwell positions along the single lumen can provide a limited ability to optimize the dosimetry. Multiple dwell positions along the one centrally-located treatment lumen of the ellipsoidal MammoSite are routinely used to appropriately deliver the prescription dose with this unique balloon.

28. Because of their single central lumen design, the MammoSite devices rely heavily on the 'fit' within the cavity and require acceptable conformance, balloon symmetry and distance from skin and rib for safe and effective dose delivery.

29. When placed appropriately, in an appropriate cavity, the MammoSite devices can achieve the dosimetric goals for breast balloon brachytherapy.

30. However, treatment options suffer when any of the parameters are not ideal. Because the MammoSite has only a single central lumen, there is a limited ability to correct for inadequate cavity conformance, balloon asymmetry, or inadequate spacing between the balloon surface and skin/rib. This means that the inability to meet and or exceed the accepted dosimetric criteria for treatment can be and is encountered by physicians in the use of the MammoSite. If the accepted dosimetric criteria can not be met, the physician's options are to either compromise ideal dosing or to explant (take out) the device and pursue another method of treatment.

THE SENORX CONTURA

31. It is my belief that the SenoRx Contura represents a significant advance in balloon brachytherapy. It takes successful components of the MammoSite balloon device, but further builds on them through its multiple offset lumen design.

32. The Contura's multiple lumens allow radiation oncologists and physicists a far greater ability to shape the dose received by a patient than the single lumen design of the MammoSite. Although the multi-lumen capability will not provide the ability to treat all eligible

patients with balloon based brachytherapy due to technical constraints, this new ability to shape the dose will allow physicians to improve dosimetry in marginally acceptable cases in which brachytherapy would have been used before the introduction of the Contura, and further allows for acceptable dosimetry in many patients for whom single lumen balloon based brachytherapy is not a viable option. Depending on the severity of deviation from acceptable placement criteria, the dosing flexibility allowed by the Contura allows dose reduction to nearby rib and skin and can correct for an asymmetric cavity shape or asymmetric balloon.

33. Although the MammoSite provides successful treatment for some select population of women, the Contura has the ability to increase the number of patients overall that can be treated with balloon-based brachytherapy. In my opinion and experience, there are patients that are treatable by (and that have been treated with) the Contura that could not have been treated by the MammoSite because of the location of the lumpectomy cavity and treatment target within the breast and its relationship to skin and rib. It is also my opinion and experience that there are patients that can be treated with the Contura in a manner that improves the dose profile (and thus the safety and effectiveness of the treatment) as compared to the treatment of that same patient by the MammoSite balloon.

34. I currently am heading a clinical study where we are fully investigating the dosimetric capabilities of the Contura, and determining on a scientific basis the extent to which it will, or will not, prove to be beneficial as compared to single central lumen devices. This study is designed as a multi-institutional IRB-approved investigation that will accrue 342 patients over an 18 month period.

35. For each patient in the study, a dosimetric plan will be devised for three types of devices: 1) a single central lumen, single dwell device; 2) a single central lumen, multi-dwell device (such as the MammoSite); and 3) a multi-lumen, multi-dwell device (i.e., the Contura). The physicians participating in the study will evaluate the three plans developed for each patient on the goals of target coverage, dose homogeneity, skin dose and rib dose, and the optimal plan will be used for treatment. Although the focus of the study lies within the dosimetric

comparison, outcome of the treatment will be followed, and data collected and analyzed regarding efficacy (disease control) and side effects (toxicity).

36. The hypothesis of the study is that the multi-lumen device will improve the ability to meet dosimetric planning goals in a minimum of 15% of patients. Based on my experience with MammoSite use and early experience with the Contura Multi-lumen balloon, I believe that the results likely will be higher, showing an ability to meet dosimetric goals in 20% or more of patients.

37. The Contura also has additional features lacking from the MammoSite balloon device that are helpful in balloon brachytherapy. For one, it has two evacuation ports that allow the physician to remove trapped air and fluid from the lumpectomy cavity to assist in the cavity's conformation to the balloon. Additionally, the Contura balloon is made from polyurethane, which is more robust than the silicone balloon of the current MammoSites and appears to have less of a problem with asymmetry.

38. The labeling of the Contura includes a warning cautioning against use if the distance between the balloon and the skin is 5mm or less. The MammoSite devices have a similar warning. These warnings were derived from the initial use of the MammoSite device where dose directly correlates with the distance from the balloon surface as a result of only having a single central lumen for radioactive source positioning. Therefore the skin distance is a surrogate for skin dose. This rule of thumb was adopted as MammoSite use was initiated when CT-based 3D treatment planning, and therefore skin dose calculation, were not yet widely available and it was safer to apply a skin thickness limitation as a way to limit skin dose. Initial recommendations to assure that the skin thickness was at a minimum of 5mm were an attempt to limit excessive dose delivered to the skin. Clinical observations and published treatment outcome of the MammoSite device actually show that a preferred skin thickness of >7mm as it correlates with a decrease in skin toxicity.

39. However, it should be clearly noted that criteria of skin thickness is simply a surrogate for skin dose and only is an issue when utilizing a single lumen device with limited ability to manipulate the dosimetry and pattern of dose delivery. Any radiation oncologist would

realize that the critical issue is the ultimate skin dose and that, with the ability associated with the multi-lumen balloon catheter to control and deliver a specific skin dose, skin thickness is no longer a relevant criteria in this regard. Although the ability to control the dose with the Contura MLB is not as dramatic as with the multicatheter brachytherapy approach, it is similar in concept. When treating with the multicatheter approach, the skin dose is carefully managed and skin thickness is disregarded and not considered beyond concerns regarding vascular and strength integrity as it would following any surgery.

40. As the Contura has offset lumens, it allows physicians to treat patients in appropriate circumstances where there is less than a 5mm between balloon and skin, because the radiation source in the Contura can be offset, limiting the dose to the skin.

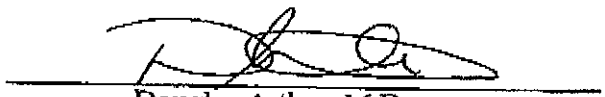
41. Although I am not aware of SenoRx promoting its device for this use, the utility of the Contura in this respect is evident from the design of the device. I personally have used the Contura in this manner to treat patients who had less than a 5mm skin thickness. Likewise, I have used the Contura's multi-lumen design to decrease rib dose when appropriate.

42. I have been asked if, in my opinion, the availability of the Contura will harm the image of balloon brachytherapy in the medical community. It absolutely will not. To the contrary, the availability of the Contura will improve the ability to meet dosimetric goals for balloon based brachytherapy and expand the number of women for whom balloon brachytherapy will be a viable treatment option.

43. It is my opinion that an injunction removing the Contura from the market would negatively impact the care of patients, negatively impact present scientific investigation and progress towards improved APBI treatment delivery, and impede investigation into the benefits of balloon brachytherapy in general, and multi-lumen balloon brachytherapy in particular.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: March 27, 2008



Douglas Arthur, M.D.

Exhibit 1

DOUGLAS WILLIAM ARTHUR

CURRICULUM VITAE

Radiation Oncology Department
P.O. Box 980058
Richmond, VA 23298-0058
(W) 804-828-7232
(H) 804-360-8182
(fax) 804-360-6042
DArthur@mcvh-vcu.edu

Curriculum Vitae
Douglas William Arthur, M.D.
March 28, 2008

CURRICULUM VITAE
March 28, 2008
DOUGLAS WILLIAM ARTHUR, M.D.

1. PERSONAL INFORMATION

1.1. Douglas W. Arthur
1.2. U.S. Citizen
1.3. Office Address: Virginia Commonwealth University
Medical College of Virginia Campus
Department of Radiation Oncology
P.O. Box 980058
Richmond, Virginia 23298-0058
Office Telephone: (804) 828-5296
e-mail – DArthur@mcvh-vcu.edu

2. CERTIFICATE LICENSURE

2.1.	1990 to Present	Virginia Board of Medicine License - #0101045501
2.2.	June 1995	Radiation Oncology Board Certification

3. EDUCATION

3.1.	8/1981 to 5/1985	Undergraduate, Dickinson College, Carlisle, PA (Bachelor of Science - major in biology, minor in physics)
3.2.	8/1985 to 5/1989	Medical School, Bowman Gray School of Medicine, Winston-Salem, NC
3.3.	7/1989 to 6/1990	Transitional Internship, Roanoke Memorial Hospital, Roanoke, VA
3.4.	7/1990 to 5/1994	Radiation Oncology Residency, Medical College of Virginia, Richmond, VA 23298-0058
3.5.	January 1994	1 month - Brachytherapy Fellowship, Memorial Sloan Kettering Cancer Center

4. SIGNIFICANT WORK EXPERIENCE/EMPLOYMENT HISTORY

4.1.	6-8/1983 & 6-8/1984	Infectious disease Branch of the National Institute of Neurological and Communicative Disorders and Stroke, Bethesda, Maryland. Internship for college - standardize enzyme-linked immunosorbent assay (ELISA) for CMV and viral antigens in connection with an AIDS study
4.2.	9-10/1987	Research with Dr. Alan Elster of the Dept. of Radiology at the Wake Forest U. University School of Medicine - funded by the National Cancer Institute
4.3.	7/1989 to 6/1990	Intern, Roanoke Memorial Hospital, Roanoke, VA
4.4.	7/1990 to 5/1994	Resident, MCV, Radiation Oncology Dept., Richmond, VA 23298-0058
4.5.	6/1993 to 12/1993	Chief Resident, MCV, Radiation Oncology Dept., Richmond, VA 23298-0058
4.6.	4/1994 to 6/1994	Clinical Instructor, MCV, Radiation Oncology Dept., Richmond, VA 23298-0058
4.7.	7/1994 to 7/2001	Assistant Professor, MCV, Radiation Oncology Dept., Richmond, VA 23298-0058
4.8.	7/2001 to 7/2007	Associate Professor, VCUMC, Radiation Oncology Dept., Richmond, VA 23298-0058
4.9.	7/2007 to present	Professor, VCUMC, Radiation Oncology Dept., Richmond, VA 23298-0058

Curriculum Vitae
Douglas William Arthur, M.D.
March 28, 2008

5. ADMINISTRATIVE EXPERIENCE

5.1.	6/1993 to 5/1994	Quality Assurance Committee, Radiation Oncology Dept., MCV
5.2.	6/1993 to 5/1994	Chief Resident
5.3.	7/1994 to 2001	Coordinator and Supervisor of departmental medical student rotation
5.4.	1996 to 2000	Medical Advisor to the training program in Radiation Therapy
5.5.	1996 to 2001	Residency Training Program Director for MCV Radiation Oncology
5.6.	1996 to Present	Chief of Brachytherapy Service
5.7.	1997 to 2001	Coordinator and Supervisor of Clinical Oncology Summer Fellowship Program
5.8.	1997 to 2002	Coordinator of Travel Grant Award Program for American Brachytherapy Society Annual Meeting
5.9.	2002 to 2003	Treasurer for American Brachytherapy Society
5.10.	2003 to 2004	Secretary for American Brachytherapy Society
5.11.	2004 to 2005	President elect for American Brachytherapy Society
5.12.	2005 to 2006	President for American Brachytherapy Society
5.13.	2006 to 2007	Chairman of the Board, American Brachytherapy Society
5.14.	2001 to 2003	Clinical Director – Department of Radiation Oncology, VCUHS
5.15.	2003 to 2005	Vice Chairman of Department of Radiation Oncology, VCU Medical Center
5.16.	2005 to 6/2006	Interim Chairman of Department of Radiation Oncology, VCU Medical Center
5.17.	4/2006 to present	Medical Director of Radiation Oncology, Henrico Doctors Hospital
5.18.	6/2006 to present	Vice Chairman of Department of Radiation Oncology, VCU Medical Center
5.19.	9/2006 to present	Associate Director of Clinical Affairs, Massey Cancer Center

6. SOCIETY MEMBERSHIPS

6.1.	1990 to 1995	Junior member of ASTRO
6.2.	1995 to Present	ASTRO
6.3.	1995 to Present	American Brachytherapy Society
6.4.	1997 to Present	Associate Member of the Massey Cancer Center
6.5.	1998 to Present	Richmond Academy of Medicine
6.6.	2000 to Present	Medical Society of Virginia
6.7.	2007 to Present	American College of Radiology

7. COMMUNITY ORGANIZATIONS

7.1. Church Membership

8. MAJOR COMMITTEES

8.1.	1995 to 2001	MCV Cancer Education Council
8.2.	1995 to 2000	Radiation Oncology consultant to the Operating Room Committee
8.3.	1996 to 1998	Departmental representative to Richmond Memorial's MSQI committee
8.4.	1996 to 2001	Residency Program Directors Council
8.5.	1996 to 2001	Memorial Regional Hospital Cancer Committee
8.6.	1996 to 2003	Quality Assurance Officer for our satellite office at Hanover Medical Park
8.7.	1998 to 2003	Brachytherapy committee for Radiation Therapy Oncology Group
8.8.	1999 to 2000	Scientific program committee for American Brachytherapy Society's

		International meeting in Washington D.C, May, 2000
8.9.	1999 to 2003	MCV Physicians Audit Committee
8.10.	2001 to 2003	Ambulatory Care Committee – Medical College of Virginia Hospitals
8.11.	2001 to 2006	Ambulatory Care Committee – Memorial Regional Medical Center
8.12.	2001 to present	Operations Committee – Dept of Radiation Oncology, VCU Medical Center
8.13.	2001 to present	Quality Assurance Committee – Dept. of Radiation Oncology, VCU Medical Center
8.14.	2003 to 2005	Attend MCVH Executive Committee Meetings for Chairman
8.15.	2005 to 6/2006	Executive Committee VCU Medical Center
8.16.	2006	MCVP overhead review committee
8.17.	2006 to present	Breast committee – Radiation Therapy Oncology Group
8.18.	2006 to present	Scientific Audit Committee for Adult Treatment Editorial Board Literature Review, NCI, PDQ (Physician Data Query)
8.19.	2007 to present	American College of Radiology's Breast Ca Appropriateness Criteria Expert Panel

9. NATIONAL RESEARCH GROUP MEMBERSHIP and ACTIVITY

9.1. Radiation Therapy Oncology Group / RTOG
- 9.1.1. Brachytherapy committee- 1998 – 2003
- 9.1.2. Breast Committee – 2006 - present

9.2. National Surgical Breast and Bowel Project (NSABP)
- 9.2.1. Radiation Oncology Advisory C Radiation Therapy Advisory Group (RTAG) for the NSABP – 2003 to present
- 9.2.2. Co–Principal Investigator, NSABP/RTOG phase III protocol, A Randomized Phase III Study of Conventional Whole Breast Radiation Therapy (WBT) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer
- 9.2.3. Radiation Oncology Principle Investigator – NSABP B-43 Phase III protocol, A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma in Situ Resected by Lumpectomy

10. INVITED SPEAKER

10.1. The Role of Radiotherapy in the Management of Breast Cancer - invited lecturer, 11th Annual Update in Mammography, Conference sponsored by the Dept. of Radiology, Medical College of Virginia, 1996.

10.2. Breast Conservation Treatment - invited CME lecturer, Riverside Hospital, Newport News VA., 1996.

10.3. Radiation Therapy and Fibrosis - invited lecturer, 4th Annual Quality of Life Conference - Cancer Rehabilitation, 1997.

10.4. Breast Conservation Treatment and Brachytherapy - an innovative approach - invited lecturer, Virginia Society of Radiologic Technology, 1997.

10.5. Breast Conservation Treatment and the use of HDR Brachytherapy - CME invited lecturer, Montgomery General Hospital, Olney, MD, 1997.

10.6. Invited speaker –"New Techniques of Radiation Therapy for Local Management of Breast Cancer" - 2nd Annual VCU/MCV Advances in Cancer Therapy 10/1998

10.7. Invited speaker – "Breast Cancer , Role of Radiotherapy" – MW Hospital, Fredricksburg, VA, 1/2000

10.8. Invited speaker – "HDR brachytherapy" – Athens, GA, 3/2000

10.9. Invited speaker – IMRT meeting – Williamsburg, VA – 2001

10.10. Faculty speaker – 1st ABS School of Breast Brachytherapy – 2/2002

10.11. Invited Speaker – Accelerated Partial Breast Irradiation, Los Angeles CA, Varian Sponsored 5/2002

10.12. Invited Speaker – 11th International Brachytherapy conference, Nucletron, 6/2002.

10.13. Invited Speaker – Accelerated Partial Breast Irradiation, New York, Varian Sponsored 11/2002

10.14. Invited Participant, Presentation – NCI meeting on Accelerated Partial Breast Irradiation, 12/2002

10.15. Panel Speaker on Accelerated Partial Breast Irradiation – ASTRO 2002

10.16. Faculty speaker – 2nd ABS School of Breast Brachytherapy, 1/2003

10.17. Invited Speaker – Proxima Therapeutics, MammoSite - Physicians Meeting 2/2003

10.18. Invited Speaker – Society of Surgical Oncology – APBI – 3/2003

10.19. Invited Speaker – Virginia Breast Cancer Foundation – 6/2003

10.20. Faculty Speaker – School of Breast Oncology, Atlanta, GA – 11/2003

10.21. Faculty Speaker – 3rd ABS School of Breast Brachytherapy – 2/2004

10.22. Faculty Speaker – ACRO annual meeting – Partial Breast Irradiation – 2/2004

10.23. Faculty Speaker – Joint ABS/GEC/ESTRO meeting – Partial Breast Irradiation – Barcelona, Spain – 5/2004

10.24. Panel Speaker - Accelerated Partial Breast Irradiation – ASTRO, Atlanta, GA, 10/2004

10.25. Invited Speaker – Mid-Atlantic Society of Radiation Oncology – Richmond, VA – 9/2004

10.26. Faculty Speaker - Accelerated Partial Breast Irradiation, Controversies in Breast Cancer Adjuvant and Neoadjuvant Therapy: New York, NY 2004

10.27. Faculty Speaker – School of Breast Oncology, Atlanta, GA – 11/2004

10.28. Faculty Speaker and expert panel member – Accelerated Partial Breast Irradiation- techniques and Future - American Society of Breast Surgeons – annual meeting, Los Angeles, CA – 3/2005

10.29. Faculty Speaker- Accelerated Partial Breast Irradiation - American Society of Breast Diseases – annual meeting , Las Vegas,4/2005

10.30. Faculty Speaker- Multi-catheter Breast Brachytherapy American Experience – Breast Brachytherapy

Workshop – GEC- ESTRO (European Brachytherapy Society) – Budapest, Hungary- 5/2005.

10.31. Faculty Speaker – American Brachytherapy Society annual meeting, San Francisco 6/2005- Breast Brachytherapy refresher course.

10.32. Invited Speaker - Partial Breast Irradiation ASCO Meeting Highlights – Pittsburgh, PA June, 2005

10.33. Invited Speaker –Advances in Accelerated Partial Breast Irradiation Background and Preparation for a National Phase III Trial - Perspectives in Breast Cancer Conference 11thannual Boston, 10/2005

10.34. Refresher course – Early Stage Breast Cancer and Accelerated Partial Breast Irradiation – ASTRO, Denver, CO 10/2005

10.35. Invited Speaker – Symposium, Partial Breast Irradiation – Should you be doing it? – Denver, CO 10/2005

10.36. Faculty Speaker – School of Breast Oncology, Atlanta, GA – 11/2005

10.37. Invited Speaker - Correct Contouring/Increasing Brachytherapy Accrual for NSABP B39 – Radiation Therapy Oncology Group meeting, Miami, 1/2006

10.38. Faculty Speaker – School of Breast Brachytherapy, American Brachytherapy Society– Las Vegas, NV 2/2006

10.39. Invited Speaker – Accelerated Partial Breast Irradiation – challenging and changing a treatment paradigm – Sun, Sand and Seeds 8th annual conference, West Palm Beach FLA, 3/2006

10.40. Faculty Speaker – American Brachytherapy Society annual meeting, Philadelphia 5/2006- Breast Brachytherapy refresher course.

10.41. Presidential address – American Brachytherapy Society annual meeting, Philadelphia 5/2006

10.42. Refresher course – Early Stage Breast Cancer and Accelerated Partial Breast Irradiation – ASTRO, Philadelphia, PA 11/2006

10.43. Faculty Speaker - Accelerated Partial Breast Irradiation - Multi-Catheter Technique - ASTRO Panel Discussion – ASTRO Philadelphia, PA, 11/2006

10.44. Faculty Speaker – Breast Cancer Symposium - Overview of radiotherapy post BCT - Partial breast irradiation: Techniques, Indications and Contraindications. Bethesda, MD 11/06

10.45. Faculty Speaker – School of Breast Oncology, Atlanta, GA – 10/2006

10.46. Faculty Speaker – Perspectives in Breast Cancer – Accelerated Partial Breast Irradiation– Charleston, SC 1/07

10.47. Faculty Speaker – Accelerated Partial Breast Brachytherapy – ACRO San Diego, Ca 2/07

10.48. Faculty Speaker – School of Breast Brachytherapy, American Brachytherapy Society– Las Vegas, NV 3/2007

10.49. Faculty Speaker - American College of Surgeons, APBI course, Annual meeting, New Orleans LA - 10/8/2007

10.50. Faculty Speaker - Adjuvant and Neoadjuvant Therapy of Breast Cancer - New York, NY - Oct. 12-14, 2007

10.51. Refresher course – Early Stage Breast Cancer and Accelerated Partial Breast Irradiation – ASTRO, Los Angeles, CA 10/28-31/2007

10.52. Faculty Speaker – School of Breast Oncology, Atlanta, GA – 10/2007

10.53. Faculty Speaker - 8th Annual Comprehensive Breast Conference UVA/VCU – Accelerated Partial Breast Irradiation update - 11/20/2007.

10.54. Faculty Speaker – Breast cancer, Best of ASTRO – 2007 ASTRO Review, University of Maryland, 1/10/2008.

10.55. Faculty Speaker – School of Breast Brachytherapy, American Brachytherapy Society– Pheonix, Az 2/2008

10.56. Invited Speaker – annual meeting American Brachytherapy Society – What is the APBI target? – Boston, MA 5/2008

11. OTHER SIGNIFICANT SCHOLARLY, RESEARCH OR ADMINISTRATIVE EXPERIENCE:

11.1. General Radiation Oncology Lecture, 2nd medical students, yearly - 1995 to 2005

11.2. **Principal Investigator -** Intramural protocol - Peri-operative HDR Brachytherapy

11.3. **Principal Investigator (for site) –** Radiation Oncology Therapy Group 95-17 protocol – Phase I-II trial of brachytherapy alone following lumpectomy for select breast cancer - and lead accrual site nationally

11.4. Invited guest on "Ask the Family Doctor" – cable TV network, Focusing on breast brachytherapy, 1998.

11.5. Invited to represent and present early experience of RTOG protocol 95-17 at the 2/98 meeting

11.6. American Brachytherapy Society Abstract review board – 1998 – present

11.7. **Co-Principal Investigator -** Endovascular Brachytherapy Protocol – Novoste sponsored

11.8. **Principal Investigator (for site) –** Phase I/II MammoSite Radiation therapy system for early stage breast cancer – Proxima Therapeutics Inc sponsored.

11.9. American Brachytherapy Society Breast Brachytherapy Panel - Formulation of guidelines – publication

11.10. Appointed Scientific Director of American Brachytherapy Society meeting 2003

11.11. Invited for Panel on Accelerated breast treatment – ASTRO 2002

11.12. Invited proctor to initiate Breast brachytherapy program – Colorado Springs, Co

11.13. Faculty - Chair of Breast Section – American Brachytherapy Society meeting May, 2002

11.14. Moderator, proffered papers Breast, ASTRO 2002

11.15. Abstract review board for American Brachytherapy Society, 1998 to present

11.16. Brachytherapy sub-committee for Radiation Therapy Oncology Group, 1998 to 2003

11.17. Faculty – American Brachytherapy Society School of Breast Brachytherapy, 2003

11.18. Scientific Director of American Brachytherapy Society Meeting 5/2003

11.19. Abstract reviewer for ASTRO *2002 to present*

11.20. Editorial Board for the American Journal of Clinical Oncology – *2003 to present*

11.21. Ad Hoc manuscript reviewer for: Radiology, Lancet Oncology, Annals of Surgical Oncology, Brachytherapy, Int J Rad Onc Bio Phys

11.22. Author of Joint Economics Committee ASTRO statement on Partial Breast Brachytherapy – 12/2003

11.23. Organized Massey Cancer Center sponsored meeting of experienced MammoSite Device users to discuss appropriate use and early toxicity – 9/2004

11.24. **Principal Investigator (for site) –** Multi-Institutional Protocol - Accelerated Partial Breast Irradiation for DCIS breast cancer with MammoSite RTS – Proxima Therapeutics sponsored

11.25. Program Chair and speaker – American Brachytherapy Society School of Breast Brachytherapy – 2/2005

11.26. Organization and management of Departmental Research Retreat – 2/2005

11.27. **Co–Principal Investigator**, NSABP/RTOG phase III protocol, A Randomized Phase III Study of Conventional Whole Breast Radiation Therapy (WBT) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer

11.28. **Principal Investigator**, RTOG phase I/II protocol, Repeat Breast Conserving Surgery and Partial Breast Irradiation for In-Breast Recurrences following Whole Breast Irradiation. – concept accepted, in development

11.29. Program Chair and speaker – American Brachytherapy Society School of Breast Brachytherapy – 2/2006

11.30. Radiation Oncology Oral Board Examiner – 2006

11.31. Program Chair and speaker – American Brachytherapy Society School of Breast Brachytherapy – 3/2007

11.32. Radiation Oncology Oral Board Examiner – 2007

11.33. Editorial board for the journal *Brachytherapy* – 2006 – present

11.34. Radiation Oncology **Principle Investigator** – NSABP B-43 Phase III protocol, A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma in Situ Resected by Lumpectomy

11.35. Visiting Professor – Wake Forest University Department of Radiation Oncology – 4/26/2007

11.36. Visiting Professor – University of Virginia, Department of Radiation Oncology – 5/25/2007

11.37. Development of Partial Breast Brachytherapy self assessment module – American Brachytherapy Society – lead responsibility of team - 12/2008

11.38. Visiting Professor – University of Maryland, Department of Radiation Oncology – 1/9/2008

11.39. Visiting Professor – Mass General Hospital, Department of Radiation Oncology – 3/4/2008

11.40. Program Chair and speaker – American Brachytherapy Society School of Breast Brachytherapy – 2/2008

12. HONORS/AWARDS

12.1. Resident Teaching Award, Dept. of Radiation Oncology – 1999-2000

12.2. Medical School teaching award – 1999-2000 – Hematology and Oncology Award

12.3. AcademicKeys Who's Who in Medical Sciences Education – 2005 –

12.4. Outstanding Teacher Pin Award – 2nd year medical school - Hematology and Oncology- 2004-2005

12.5. Top Doc's – Radiation Oncologist - Richmond Magazine, 2004

12.6. Best Doctors in America - 2005-2006

12.7. Top Doc's – Radiation Oncologist – Richmond Magazine, 2006

12.8. Best Doctors in America – 2007-2008

13. PUBLICATIONS

13.1. Chu AB, Nerurkar L, **Arthur D**, et al. Comparison of Detection of Oligoclonal Immunoglobulin G Bands by Coomasie Blue and Silver Stain. *Diagn Immunol* 3:97-98; 1985.

13.2. Elster AD, **Arthur DW**. Intracranial Hemangioblastomas: CT and MR findings in Eight Cases. *The Journal of Computer Assisted Tomography*. 12:736-739; 1988

13.3. **Arthur DW**, Kaufman N, Schmidt-Ullrich R, Simpson P, Hill M, Ali M. Heuristically Derived Tumor Burden Score as a Prognostic Factor for Stage IIIB Carcinoma of the Cervix. *Int J Radiat Oncol Biol Phys* 31:743-751; 1995.

13.4. Neff PT, Bear HD, Pierce CV, Grimes MM, Fleming MD, Neifeld JP, **Arthur DW**, Horsley JS, Lawrence W, Kornstein MJ. Long-Term Results of Breast Conservation Therapy for Breast Cancer. *Annals of Surgery* 223:709-717; 1996.

13.5. **Arthur DW**, Zwicker RD, Huang D, Schmidt-Ullrich R. Electron/Photon Matched Field Technique for Treatment of Orbital Disease. *Int J Radiat Oncol Biol Phys* 37:469-474; 1997.

13.6. Kavanagh BD, Gieschen HL, Schmidt-Ullrich RK**, Arthur D**, Zwicker RD, Kaufman N, Goplerud DR, Segretti EM, West RJ. A Pilot Study of Concomitant Boost Accelerated Superfractionated Radiotherapy for Stage III Cancer of the Uterine Cervix. *Int J Radiat Oncol Biol Phys* 38:561-568; 1997.

13.7. **Arthur DW**, Kavanagh BD, Schmidt-Ullrich RK. Re: Hsu et al. 1998; 40(2):405-410 *Int J Radiat Oncol Biol Phys* 42:1177-8, 1998

13.8. Zwicker RD, **Arthur DW**, Kavanagh BD, Mohan R, Schmidt-Ullrich RK. Optimization of planar high dose rate implants. *Int J Radiat Oncol Biol Phys* 44:1171-1177, 1999.

13.9. **Arthur DW**, Schmidt-Ullrich RK, Friedman RF, Wazer DE, Kachnic LA, Amir C, Bear HB, Hackney MH, Smith TJ, Lawrence W. Accelerated superfractionated radiotherapy for inflammatory breast carcinoma: complete response predicts outcome and allows for breast conservation. *Int J Radiat Oncol Biol Phys* 44:289-296,1999.

13.10. Kramer BA, **Arthur DW**, Ulin K, Schmidt-Ullrich RK, Zwicker RD, Wazer DE. Cosmetic outcome in patients receiving an interstitial implant as part of breast-conservation therapy. *Radiology* 213:61-66, 1999.

13.11. **Arthur DW**, Arnfield MR, Warwicke LA, Morris MM, Zwicker RD. Internal Mammary Node Coverage – An Investigation of Presently Accepted Techniques. *Int J Radiat Oncol Biol Phys* 48:139-46, 2000.

13.12. Manning MA, **Arthur DW**, Schmidt-Ullrich RK, Arnfield MR, Amir C, Zwicker RD. Interstitial high dose rate brachytherapy boost: the feasibility and cosmetic outcome of a fractionated outpatient delivery scheme. *Int J Radiat Oncol Biol Phys* 48:1301-6, 2000.

13.13. Manning MA, Zwicker RD, **Arthur DW**, Arnfield MR. Biologic treatment planning for high-dose-rate brachytherapy. *Int Radiat Oncol Biol Phys* 49:839-845, 2001.

13.14. Nag S, Kuske RR, Vicini F, **Arthur DW**, Zwicker RD. The American Brachytherapy Society recommendations for brachytherapy for carcinoma of the breast. *Oncology* 15(2): 195-205, 2001.

13.15. Kavanagh BD, Segreti EM, Koo D, Amir C, **Arthur D**, Wheelock J, Cardinale RM, Schmidt-Ullrich RK. Long-term local control and survival after concomitant boost accelerated radiotherapy for locally advanced cervix cancer. *Am J Clin Oncol*. 24:113-9, 2001.

13.16. Lutz S, Norrell R, Bertucio C, Kachnic L, Johnson C, **Arthur D**, Schwarz M, Palardy G. Symptom frequency and severity in patients with metastatic or locally recurrent lung cancer: a prospective study using the Lung Cancer Symptom Scale in a community hospital. *J Palliat Med*. 4:157-65, 2001

13.17. Arnfield MR, Lin PS, Manning MA, **Arthur DW**, Kavanagh BD, Zwicker RD, Schmidt-Ullrich RK. The effect of high-dose-rate brachytherapy dwell sequence on cell survival. *Int J Radiat Oncol Biol Phys.* 52:850-857, 2002.

13.18. Keisch M, Vicini F, Kuske RR, Hebert M, White J, Quiet C, **Arthur D**, Scroggins T, Streeter O. Initial clinical experience with the MammoSite breast brachytherapy applicator in women with early-stage breast cancer treated with breast-conserving therapy. *Int J Radiat Oncol Biol Phys.* 55:289-93; 2003.

13.19. **Arthur DW**, Vicini FA, Kuske RR, Wazer DE, Nag S. Accelerated Partial Breast Irradiation: an update report from the American Brachytherapy Society. *Brachytherapy*. 2:124-130; 2003.

13.20. Vicini FA, **Arthur DW**, Wazer DE. Inconsistency, perspective, double talk, and false virtue. *Brachytherapy*. 2:121-3;2003.

13.21. **Arthur DW**, Koo D, Zwicker RD, Tong S, Bear HD, Kaplan BJ, Kavanagh BD, Warwicke LA, Holdford D, Amir C, Archer KJ, Schmidt-Ullrich R. Partial Breast Brachytherapy Following Lumpectomy: a Low Dose Rate and High Dose Rate Experience. *Int J Radiat Oncol Biol Phys.* 56:681-689; 2003.

13.22. George R, Keall PJ, Kini VR, Vedam SS, Siebers JV, Wu Q, Lauterbach MH, **Arthur DW**, Mohan R. Quantifying the effect of intrafraction motion during breast IMRT planning and dose delivery. *Med Phys*. 30:552-62;2003.

13.23. Vicini F, **Arthur D**, Polgar C, Kuske R. Defining the efficacy of accelerated partial breast irradiation: the importance of proper patient selection, optimal quality assurance, and common sense. *Int J Radiat Oncol Biol Phys*. 57:1210-3;2003.

13.24. **Arthur D**. Accelerated partial breast irradiation: a change in treatment paradigm for early stage breast cancer. *J of Surg Onc*.84:185-191;2003.

13.25. Wallner P, **Arthur D**, Bartelink H, Connolly J, Edmundson G, Giuliano A, Goldstein N, Hevezi J, Julian T, Kuske R, Lichter A, McCormick B, Orecchia R, Pierce L, Powell S, Solin L, Vicini F, Whelan T, Wong J, Coleman CN; Workshop Participants. Workshop on partial breast irradiation: state of the art and the science, Bethesda, MD, December 8-10, 2002. *J Natl Cancer Inst.* 96:175-84; 2004.

13.26. Kuerer HM, **Arthur DW**, Haffty BG. Repeat Breast-Conserving Surgery for In-Breast Local Breast Cancer Recurrence: Potential Role of Partial Breast Irradiation *Cancer*. 100:2269-80;2004

13.27. Shah NM, Tenenholz T, **Arthur D**, DiPetrillo T, Bornstein B, Cardarelli G, Zheng Z, Rivard MJ, Kaufman S, Wazer DE. MammoSite and interstitial brachytherapy for accelerated partial breast irradiation: factors that affect toxicity and cosmesis. *Cancer*. 101:727-34;2004.

13.28. **Arthur DW**, Vicini FA. MammoSite RTS: the reporting of initial experiences and how to interpret. *Ann Surg Oncol*. 11:723-4;2004.

13.29. Vicini F, Edmundson G, **Arthur D**. In regard to Poti et al.: Partial breast irradiation with interstitial (60)co brachytherapy results in frequent grade 3 or 4 toxicity: Evidence based on a 12-year follow-up of 70 patients *Int J Radiat Oncol Biol Phys* 58:1022-33;2004.

13.30. Vicini FA, **Arthur DW.** Breast Brachytherapy: North American Experience. *Seminars of Radiation Oncology*. 15(2);2005.

13.31. **Arthur DW,** Vicini FA. Accelerated Partial Breast Irradiation as a part of Breast Conservation Therapy. *J Clin Onc*. 23:1-10; 2005

13.32. **Arthur DW**, Morris MM, Vicini FA. Breast Cancer – New Radiation Options. *Oncology (Huntingt)*. Nov;18(13):1621-9; discussion 1629-30, 1636-38; 2004

13.33. Schmidt-Ullrich P, Todor DA, Cuttino LW, **Arthur DW**. Virtual Planning of Multicatheter Brachytherapy Implants for Accelerated Partial Breast Irradiation. Conf Proc IEEE Eng Med Biol Soc. 5:3124-3127;2004.

13.34. Cuttino LW, **Arthur DW**, Todor D, Tong S. Ct-guided multi-catheter insertion technique for partial breast brachytherapy: reliable target coverage and dose homogeneity *Brachytherapy*. 2005;4:10-7.

13.35. Alpert TE, Kuerer HM, **Arthur DW**, Lannin DR, Haffty BG. Ipsilateral Breast Tumor Recurrence following Breast Conservation Therapy: Outcomes of Salvage Mastectomy vs. Salvage Breast Conserving Surgery and Prognostic Factors for Salvage Breast Preservation. *Int J Radiat Oncol Biol Phys*. 63:845-51;2005

13.36. Keisch M, **Arthur DW**. Current perspective on the MammoSite Radiation Therapy System – a balloon breast brachytherapy applicator. *Brachytherapy*. 4:177-80;2005.

13.37. Vicini F, Winter K, Straube W, Wong J, Pass H, Rabinovitch R, Chafe S, **Arthur D**, Petersen I, McCormick B. A phase I/II trial to evaluate three dimensional conformal radiation therapy (3D-CRT) confined to the region of the lumpectomy cavity for stage I/II breast carcinoma: Initial report of feasibility and reproducibility of radiation therapy oncology group (RTOG) study 0319. *Int J Radiat Oncol Biol Phys*. 63:1531-1537;2005.

13.38. Patel RR, **Arthur DW.** The Emerging Role of Brachytherapy in Radiation Therapy - *Hematol Oncol Clin North Am*. 20:97-118;2006

13.39. Wazer DE, Kaufman S, Cuttino L, Dipetrillo T, **Arthur DW**. Accelerated partial breast irradiation: an analysis of variables associated with late toxicity and long-term cosmetic outcome after high-dose-rate interstitial brachytherapy. *Int J Radiat Oncol Biol Phys*. 64:489-95;2006.

13.40. Kuske RR, Winter K, **Arthur D**, Bolton J, Rabinovitch R, White J, Hanson W, Wilensick RM. A Phase II Trial of Brachytherapy Alone Following Lumpectomy for Select Breast Cancer: Toxicity Analysis of RTOG 95-17. *Int J Rad Onc Biol*. 65:45-51;2006

13.41. Benitez PR, Streeter O, Vicini F, Mehta V, Quiet C, Kuske R, Hayes MK, **Arthur D**, Kuerer H, Freedman G, Keisch M, Dipetrillo T, Khan D, Hudes R. Preliminary results and evaluation of MammoSite balloon brachytherapy for partial breast irradiation for pure ductal carcinoma in situ: a phase II clinical study. Am J Surg. 192:427-33;2006.

13.42. Cuttino LW, Todor D, Pacyna L, Peck-Sun L, **Arthur DW**. 3D Conformal External Beam Radiotherapy (3D-CRT) for Accelerated Partial Breast Irradiation (APBI): What is the Correct Prescription Dose? *Am J Clin Oncol* 29:474-8;2006.

13.43. **Arthur DW**, Cuttino LW, Neuschatz AC, Koo DT, Morris MM, Bear HD, Kaplan BJ, Dawson K, Wazer DE. Tumor bed boost omission following negative re-excision in breast conservation treatment. *Annals of Surgical Oncology*13:794-801;2006.

13.44. Dogan N, Cuttino LW, Lloyd R, Bump E, **Arthur DW**. Optimized dose coverage of regional lymph nodes in breast cancer: The role of intensity modulated radiation therapy. Int J Radiat Oncol Biol Phys. 15:1238-1250;2007.

13.45. Ibbott GS, Hanson WF, O'Meara E, Kuske RR, **Arthur D**, Rabinovitch R, White J, Wilenzick RM, Harris I, Tailor RC. Dose specification and quality assurance of radiation therapy oncology group protocol 95-17; a cooperative group study of iridium-192 breast implants as sole therapy. Int J Radiat Oncol Biol Phys. 69:1572-1578;2007.

13.46. Benitez PR, Keisch ME, Vicini F, Stolier A, Scroggins T, Walker A, White J, Hedberg P, Hebert M, **Arthur D**, Zannis V, Quiet C, Streeter O, Silverstein M. Five-year results: the initial clinical trial of MammoSite balloon brachytherapy for partial breast irradiation in early-stage breast cancer. Am J Surg. 194:456-462;2007.

13.47. Chang M, Arthur DW. Post-mastectomy Radiation - When will you offer treatment? Breast Diseases: A Year Book Quarterly, 2007.

13.48. Cuttino LW, Keisch M, Jenrette JM, Dragun AE, Prestidge BR, Quiet CA, Vicini FA, Rescigno J, Wazer DE, Kaufman SA, Ramakrishnan VR, Patel R, **Arthur DW**. Multi-institutional Experience Using the MammoSite Radiation Therapy System in the Treatment of Early-Stage Breast Cancer: 2-Year Results. Int J Radiat Oncol Biol Phys. 2007 Nov 23; [Epub ahead of print]

13.49. McIntosh A, Read PW, Khandelwal SR, **Arthur DW**, Turner AB, Ruchala KJ, Olivera GH, Jeswani S, Sheng K Evaluation of coplanar partial left breast irradiation using tomotherapy-based topotherapy Int J Radiat Oncol Biol Phys. 2008 (accepted for publication)

13.50. **Arthur DW**, Winter K, Kuske RR, Bolton J, Rabinovitch R, White J, Hanson WF, Wilenzick RM, McCormick B. A Phase II Trial of Brachytherapy Alone Following Lumpectomy for Select Breast Cancer: tumor control and survival outcomes of RTOG 95-17. Int J Radiat Oncol Biol Phys. 2008 (accepted for publication)

14. SCIENTIFIC MEETING PRESENTATIONS / PUBLISHED ABSTRACTS

14.1. **Arthur D**, Kaufman N, Johnson C, Ali M: Reaction of Treatment Parameters To Failure Patterns And Complications in Radiotherapy of Stage III & IV-A Carcinoma of The Uterine Cervix. Accepted and presented as poster - ASTRO meeting, Wash. DC, (abstract) *Int J Radiat Oncol Biol Phys*. supplement 1991.

14.2. **Arthur D**, Zwicker RD, Huang D, Schmidt-Ullrich R: Matched Photon/Electron Field Technique for Lens-Sparing Irradiation of Orbit. Accepted and presented by Huang D at the Fletcher Society Meeting, 1992.

14.3. **Arthur D**, Kaufman N, Schmidt-Ullrich R, Simpson P, Hill M, Ali M: Heuristically Derived Tumor Burden Score as Prognostic Factor for Stage IIIB Carcinoma of the Cervix. Oral presentation - 76th Annual Meeting of the American Radium Society, Bermuda, 1994.

14.4. Johnson C, Schmidt-Ullrich R, **Arthur D**, Huang D, Duffy E: Standard Once-Daily versus Thrice-Daily Concomitant Boost Accelerated Superfractionated Irradiation for Advanced Squamous Cell Carcinoma of the Head and Neck: Preliminary Results of a Prospective Randomized Trial. Oral presentation , ASTRO meeting, Miami FL, *Int J Radiat Oncol Biol Phys*. Supplement, 1995.

14.5. **Arthur D,** Wazer D, Kramer B, Schmid C, Ruthazer R, Ulin K, Zwicker R, Schmidt-Ullrich R. Factors Determining Outcome in Patients Treated with Interstitial Implantation as a Radiation Boost for Breast Conservation Therapy. Oral presentation - 19th Annual American Brachytherapy Society Meeting, Palm Beach FL, 1997.

14.6. Lutz ST, Norrell R, Johnson CR, Kachnic LA, **Arthur DW**, Huang DT. Early Results of a Prospective Quality of Life Analysis Using the Lung Cancer Symptom Scale (LCSS) in Patients Receiving Radiation Therapy (XRT) for Lung Cancer in the Community Hospital Setting. (abstract*) Int J Radiat Oncol Biol Phys* 39:198; 1997.

14.7. Kavanagh BD, Segretti, EM, Koo DT, Amir C, **Arthur DW**, Kachnic LA, Schmidt-Ullrich RK, Goplerud DR, West RJ. Prospective Evaluation of a Clinical Tumor Burden Score for Locally Advanced Cervix Cancer. Abstract accepted for poster presentation in American Radium Society meeting 1998.

14.8. Kavanagh BD, Segretti, EM, Koo DT, Kachnic LA, **Arthur DW**, Schmidt-Ullrich RK, West RJ. Acute toxicity from simultaneous pelvic and para-aortic radiotherapy for gynecologic malignancy. Abstract accepted for poster presentation in American Radium Society meeting 1998.

14.9. **Arthur DW**, Friedman RF, Wazer DE, Kachnic LA, Bear HB, Lawrence W, Hackney MH, Smith T, Schmidt-Ullrich RK. Induction chemotherapy and accelerated superfractionated radiotherapy for inflammatory breast carcinoma: complete response predicts outcome and allows for breast conservation. Oral presentation at the American Radium Society meeting, 1998.

14.10. Kramer BA, **Arthur DW**, Ulin K, Zwicker RW, Schmidt-Ulrich RK, Wazer DE. Cosmesis in patients receiving an interstitial implant as part of breast conservation therapy. Oral presentation at RSNA, 1998.

14.11. Manning M, **Arthur DW**, Arnfield M, Zwicker RW. Four-dimensional treatment planning for high dose rate brachytherapy: a biologic model. Oral presentation at the American Brachytherapy Society meeting, 1999.

Curriculum Vitae
Douglas William Arthur, M.D.
March 28, 2008

14.12. **Arthur DW**, Arnfield MR, Warwicke LA, Morris MM, Zwicker RD. Internal Mammary Node Coverage – An Investigation of Presently Accepted Techniques. Oral Presentation ASTRO 1999, (abstract) *Int J Radiat Oncol Biol Phys* 45:26, 1999.

14.13. Hess RO, Manning MA, Arthur DW. Results of the 1999 association of residents in radiation oncology (ARRO) survey of brachytherapy training. Poster 2000 International Meeting of the American Brachytherapy Society, *Radiotherapy and Oncology* 55:162, 2000.

14.14. Kini VR, Kavanagh BD, **Arthur DW**, Al-Ani A, Manning MA, Hagan M. Optimization Surveillance schedules following radiotherapy for prostate cancer based on a cost-benefit analysis. Poster presentation 2000 International Meeting of the American Brachytherapy Society – Poster 2000 International Meeting of the American Brachytherapy Society, *Radiotherapy and Oncology* 55:131, 2000.

14.15. Manning MA, **Arthur DW**, Schmidt-Ullrich RD, Arnfield MR, Zwicker RD. Cosmetic outcome following high dose rate (HDR) and low dose rate (LDR) interstitial bracytherapy boost (IBB) in high risk early stage breast cancer. Poster presentation 2000 International Meeting of the American Brachytherapy Society, *Radiotherapy and Oncology* 55:97, 2000.

14.16. **Arthur DW**, Warwicke LA, Zwicker RD, Holdford D, Manning MA, Arnfield MR. Breast brachytherapy – A method of catheter placement offering improvements in cost, time, safety and accuracy. Poster presentation 2000 International Meeting of the American Brachytherapy Society, Recipient of the Judith Stitt Best Poster Award, *Radiotherapy and Oncology* 55:95, 2000.

14.17. Hess R, Morris M, Warwicke L, **Arthur D**, Amir C. Radiation Therapy for Invasive Thymoma. Oral Presentation RSNA 2001, *Radiology*. 221(p):374, 2001.

14.18. Keisch ME, Kuske RR, Toonkel LM, Vicini FA, Hebert ME, **Arthur DW**, White JR, Quiet CA. A prospective phase I trial of an implantable balloon applicator for breast brachytherapy. Oral Presentation RSNA 2001, *Radiology*. 221(p):278, 2001.

14.19. Kuske RR, Martin B, Hanson W, **Arthur D**, Rabinovitch R, White J, Wilenzick RJ, Harris I, Tailor R, Davis D. Quality assurance and reproducibility on RTOG 95-17: A phase II trial of brachytherapy alone for select breast cancers. Oral Presentation RSNA 2001, *Radiology*. 221(p):279, 2001.

14.20. Keall P, Arnfield M, Tong S, Lauterbach M, **Arthur D**, Mohan R. Breast IMRT and the PTV Concept. Oral Presentation, AAPM 2001, *Medical Physics*. 28:1205, 2001.

14.21. Hanson W, Martin B, Kuske R, **Arthur D**, Rabinovitch R, White J, Wilenzik R, Harris I, Tailor R, Davis D. Dose Specification and Quality Assurance of RTOG 95-17, A cooperative Group Study of 192Ir Breast Implants as Sole Therapy. Oral Presentation, AAPM 2001, *Medical Physics*. 28:1297, 2001.

14.22. Keall PJ, Arnfield MR, **Arthur DW**, Lloyd R, Lauterbach MH, Siebers JV, Wu Q, Mohan R. An IMRT Technique to Reduce the Heart and Lung Dose for Early Stage Breast Cancer. Int *J Radiat Oncol Biol Phys*. 51:247, supplement 1, 2001.

14.23. Kini VR, Vedam SS, Keall PJ, **Arthur DW**, Mohan R. A Dynamic Non-Invasive Technique for predicting Organ Motion in Respiratory-Gated Radiotherapy of the Chest. *Int J Radiat Oncol Biol Phys*. 51:25, supplement 1, 2001.

14.24. **Arthur DW**, Warwicke LA, Arnfield MR, Zwicker RD, Holdford D, R.N., Kavanagh BD, Bear HD, Karp SE, Kaplan BJ, Schmidt-Ullrich RK, Recall Reactions And Early Breast Fibrosis With The Use Of Adriamycin Following Lumpectomy And Brachytherapy Only For Early Stage Breast Cancer. . *Int J Radiat Oncol Biol Phys*. 51:159, supplement 1, 2001.

14.25. George R, Keall P, Kini V, Vedam S, Siebers J, Wu Q, Lauterbach M, **Arthur D**, Mohan R. Quantifying the effect of intrafraction motion during breast IMRT planning and delivery. *Medical Physics* 2002:29;1347.

14.26. Koo D, **Arthur DW**, Neuschatz AC, Wazer DE, Cuttino LW, Amir C, Morris MM, Schmidt-Ullrich RK. Outcomes in

Early-Stage breast cancer patients treated with initial breast-conserving surgery followed by negative re-excision and radiation therapy without a tumor bed boost. *Int J Radiat Oncol Biol Phys.* 2002:54;6 supplement.

14.27. Kuske RR, Winter K, **Arthur D**, Bolton J, Rabinovitch R, White J, Hanson W, Wilenzik RM. A phase I/II trial of brachytherapy alone following lumpectomy for select breast cancer: toxicity analysis of Radiation Therapy Oncology Group 95-17 *Int J Radiat Oncol Biol Phys.* 2002:54;146 supplement.

14.28. Wu Q, **Arthur D**, Benedict S, Tong S, Wu Y, Hagan M. Intensity-Modulated radiotherapy for prostate cancer treatment with nodal coverage. *Int J Radiat Oncol Biol Phys*. 2002:54;2192 supplement.

14.29. Cuttino LW, **Arthur DW**, Todor D, Tong S. Ct-guided multi-catheter insertion technique for partial breast brachytherapy: reliable target coverage and dose homogeneity *Brachytherapy*. 1;2003.

14.30. Todor D, **Arthur DW**, Cuttino LW. Dosimetric assessment of the MammoSite RTS^{tm} radiation therapy system. *Brachytherapy*. 1;2003.

14.31. **Arthur DW**, Wazer DE, Koo D, Shah N, Berle L, Cuttino L, Yunes M, Rivard M, Todor D, Tong S, Tenenholz T, DiPetrillo T. The importance of dose volume histogram evaluation in partial breast brachytherapy: a study of dosimetric parameters. *Int J Radiat Oncol Biol Phys.* 57(2 Suppl):S361-2;2003.

14.32. Todor DA, **Arthur DW**, Cuttino LW. Volume cluster analysis: a new technique for describing the dose homogeniety of high dose rate breast brachytherapy implants. *Int J Radiat Oncol Biol Phys*.57(2 Suppl):S315-6;2003.

14.33. Keisch M, Vicini F, Kuske R, Hebert M, White J, Quiet C, **Arthur D**, Scroggins T, Streeter O. Two-year outcome with the mammosite breast brachytherapy applicator: factors associated with optimal cosmetic results when performing partial breast irradiation. *Int J Radiat Oncol Biol Phys.* 57(2 suppl):S315;2003.

14.34. Vicini F, Winter K, Wong J, Pass H, Chafe S, Rabinovitch R, **Arthur D**, Petersen I, McCormick B. A Phase I/II Trial To Evaluate Three Dimensional Conformal Radiation Therapy (3D-CRT) Confined To The Region Of The Lumpectomy Cavity For Stage I/ II Breast Carcinoma. RTOG 0319. *San Antonio Breast Cancer Symposium, 12/2004.*

14.35. Cuttino L, Todor D, **Arthur DW**, et al, 3d Conformal External Beam (3d-Crt) For Accelerated Partial Breast Irradiation (Apbi): What Is The Correct Prescription Dose? *ASTRO 2004*

14.36. Lerma F, Kelley J, **Arthur DW** 3D Monte Carlo-Based Treatment Planning Evaluation of Intracavitary HDR Balloon catheter Brachytherapy- *AAPM 2005 meeting*

14.37. Todor D, Cuttino L, Pacyna L, **Arthur DW** Whole Breast (WB) vs. Accelerated Partial Breast Irradiation (APBI): Are They Radiobiologically Equivalent? – *ASTRO 2005*

14.38. Cuttino L, **Arthur D**, Keisch M, Jenrette J, Prestidge B, Quiet C, Vicini F, Resigno J, Wazer D, Patel R. Multi-institutional Experience Using the MammoSite Radiation Therapy System (RTS) in the Treatment of Early-stage Breast Cancer: 2 year results – *ASTRO 2006*

14.39. **Arthur DW**, Winter K, Kuske RR, Bolton J, Rabinovitch R, White J, Hanson WF, Wilenzick RM, McCormick B. A Phase II Trial of Brachytherapy Alone Following Lumpectomy for Select Breast Cancer: tumor control and survival outcomes of RTOG 95-17 – *ASTRO 2006*

15. BOOKS CHAPTERS

15.1. David E. Wazer, MD, **Douglas W. Arthur, MD**. Breast: Stage Tis. *included in: Principles and Practice of Radiation Oncology 4th edition*, Perez C, Brady L, Halperin E, Schmidt-Ullrich RS (editors) - Philadelphia, PA. JB Lippincott , 2003.

15.2. Frank A. Vicini, M.D., **Douglas Arthur, M.D**. John Wong, PhD., Larry Kestin, M.D. Intensity Modulated Radiation in the Treatment of Breast Cancer- *included in: Intensity Modulated Radiation Therapy*, Mundt AJ, Toeske JC (editors) Ontario, BC Decker Inc. , 2005

15.3. **Douglas W Arthur, MD**, Frank A Vicini, MD, Monica Morris, MD. Breast IMRT. In: *Image Guided IMRT*. Bortfeld, T.; Schmidt-Ullrich, R.; De Neve, W.; Wazer, D.E (editors) – Berlin Heidelberg, Springer-Verlag, 2006

15.4. **Douglas Arthur MD**, Frank Vicini MD, David Wazer MD. Who is a candidate for APBI? *included in: Accelerated Partial Breast Irradiation: Techniques and Clinical Implementation.* David Wazer MD, Douglas W Arthur MD, Frank Vicini (editors) - Berlin Heidelberg, Springer-Verlag – 2006

15.5. (Senior author) Laurie Cuttino MD, **Douglas W Arthur MD**. The Virginia Commonwealth University (VCU) Technique of Interstitial Brachytherapy. *included in: Accelerated Partial Breast Irradiation: Techniques and Clinical Implementation.* David Wazer MD, Douglas W Arthur MD, Frank Vicini (editors) - Berlin Heidelberg, Springer-Verlag – 2006

15.6. (Senior author) Joseph Kelly MD, PhD, **Douglas W Arthur MD.** Future directions: Phase III Co-operative Group trials. *included in: Accelerated Partial Breast Irradiation: Techniques and Clinical Implementation.* David Wazer MD, Douglas W Arthur MD, Frank Vicini (editors) - Berlin Heidelberg, Springer-Verlag – 2006

15.7. **Douglas W Arthur, MD,** Frank A Vicini, MD. CT based implant technique after open-cavity surgery: The American Experience. *included in: Partial Breast Irradiation with Multicatheter Brachytherapy* Vratislav Strnad, MD, Oliver Ott, MD, (editors) – Munich, W. Zuckschwerdt Verlag – 2006.

15.8. **Douglas W Arthur, MD**, Frank A Vicini, MD Clinical Results: American experience. *included in: Partial Breast Irradiation with Multicatheter Brachytherapy* Vratislav Strnad, MD, Oliver Ott, MD, (editors) – Munich, W. Zuckschwerdt Verlag – 2006

15.9. **Douglas W Arthur, M.D.,** Frank A Vicini, M.D. Non-Invasive Breast Disease. *included in: Clinical Radiation Oncology, second edition.* Leonard L Gunderson, MD, Joel E Tepper, MD (editors) – Philadelphia, PA, Churchhill Livingston Elsevier – 2007

15.10. Frank A Vicini, M.D., Daniel Krauss, M.D., **Douglas Arthur, M.D**. Breast Cancer – Stages I and II Tailored Radiotherapy –Technical Aspects included in: *Breast Cancer Management in the Era of Molecular Medicine* Piccart, M.J., Wood, M.D., W.C., Hung, M.-C., Solin, L.J., Cardoso, F. (editors), Springer, 2007.

15.11. David E. Wazer, MD, **Douglas W. Arthur, MD**. Breast: Stage Tis. In: Principles and Practice of Radiation Oncology 5th edition. Philadelphia, PA. JB Lippincott , - 2007.

15.12. (Senior author) Joseph Kelly MD, PhD, Laurie Cuttino MD, Frank Vicini MD, **Douglas W Arthur M.D**. Breast Brachytherapy. In: Brachytherapy: Techniques and Applications edited by Phillip Devlin, MD - Lippincott Williams & Wilkins - 2007.

16. BOOKS EDITED

Curriculum Vitae
Douglas William Arthur, M.D.
March 28, 2008

16.1. Accelerated Partial Breast Irradiation: Techniques and Clinical Implementation. - David Wazer MD, **Douglas W Arthur MD,** Frank Vicini MD (editors) - Berlin Heidelberg, Springer-Verlag – 2006

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On March 28, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF DOUGLAS ARTHUR, M.D. IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on March 28, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Counterdefendants.

Case No. 08-CV-0133 RMW

DECLARATION OF PHILIP Z. ISRAEL, M.D. IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Date: April 21, 2008
Time: 2:00 p.m.
Courtroom: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

I, Philip Z. Israel, M.D., declare that:

BACKGROUND

1. The facts set forth below in this declaration are based on my personal knowledge, and if called as a witness, I could and would testify competently to those facts.

2. I am the Director of The Breast Center in Marietta, Georgia, and a Clinical Associate Professor in the Department of Surgery at the University of Tennessee College of Medicine, Chattanooga Unit. I am a breast surgery oncologist. My practice is focused on treating women with breast cancer.

3. My complete educational and employment background are described in my C.V., which is attached hereto as Exhibit 1. In summary, I received my undergraduate and medical degrees from Emory University, in 1957 and 1961, respectively. I completed my internship and residency in general surgery at Emory University Hospital. I have practiced surgery since 1968, and in 1986 I opened The Breast Center, where I remain to this date.

4. I am involved with numerous organizations related to my practice, including the American Society of Breast Surgeons and the Society of Surgical Oncology. I am the Past Chairman of the Board of Directors of the American Society of Breast Surgeons.

5. I have not testified in any trials during the past four years. I have testified in depositions in the following cases during the last four years:

a. *Gorman v. Page* (Aug. 13, 2007): Deposition testimony for defendant in medical malpractice case alleging erroneous diagnosis of breast cancer.

b. *Krebs v. Deweese* (May 23, 2007): Deposition testimony for defendant in medical malpractice case alleging misdiagnosis of breast cancer.

c. *Haj v. Curtis* (Nov. 16, 2006): Deposition testimony for defendant in medical malpractice case alleging failure to diagnose breast cancer.

d. *Ison v. Peterson* (July 31, 2006): Deposition testimony for defendant in medical malpractice case alleging failure to diagnose breast cancer.

6. I am being compensated for my time in this matter at my usual rate of $400 per hour. My compensation does not depend on the outcome of this litigation.

ROLE OF A BREAST SURGERY ONCOLOGIST

7. As a breast surgery oncologist, I am responsible for all of the surgical treatment associated with breast cancer, including biopsies, lumpectomies, and mastectomies.

8. I am usually the first to deal with a patient after she is diagnosed with breast cancer. In that capacity, I work with the patient to develop the most appropriate course of treatment. One of the decisions I make in this process is whether a patient is a candidate for balloon brachytherapy, using a device such as the MammoSite® Radiation Therapy System ("MammoSite") or the Contura™ Multi-Lumen Balloon ("Contura"). In making this decision, I take into account factors such as the severity of the cancer, and the size, shape, and location of the tumor.

9. If I determine that a patient is a candidate for balloon brachytherapy, and the patient elects to undergo that type of treatment, I send her to a radiation oncologist for an opinion. If the radiation oncologist agrees, the patient is sent back to me. After completing the lumpectomy, I implant the selected device. The patient then undergoes approximately five days of radiation treatment, and the radiation oncologist generally removes the device after the final treatment. I then follow-up with the patient to ensure that the treatment was successful.

EXPERIENCE WITH BALLOON BRACHYTHERAPY

10. In my practice, I have been both an early adopter and a strong supporter of balloon brachytherapy.

11. Traditionally, after a doctor removed a malignant lesion in a woman's breast through a process known as a lumpectomy, the whole breast required up to six weeks of radiation to the remaining breast tissue in order to minimize the possibility of a tumor recurrence.

12. Devices like the MammoSite and Contura allow doctors to target the at-risk tissue surrounding the site of the lumpectomy with a high dose rate of radiation. This method dramatically reduces the treatment time from roughly six weeks to several days. As a result, patients who undergo treatment with these devices benefit from an enhanced quality of life following a lumpectomy and experience much less interruption in their normal daily activities.

The devices also allow more targeted treatment of breast tissue (as compared to external beam radiation), with less trauma (as compared to traditional interstitial approaches).

13. I was one of the first breast surgery oncologists in the country to begin using the MammoSite in my practice. In 2001 and 2002, I assisted Proxima Therapeutics in attaining FDA approval for the device. The FDA wanted to know more about fluid buildup in the lumpectomy cavity associated with the MammoSite. The data I provided helped satisfy the FDA that the level of fluid buildup was not problematic. In August 2002, I implanted one of the first MammoSite devices in the country in one of my patients. Between 2002 and 2007, I enthusiastically promoted the MammoSite and was one of the most frequent users of the device in the country. I also served on the faculty for a Proxima-sponsored national educational meeting of physicians relating to the MammoSite, at the request of predecessors to the Plaintiffs.

14. In addition to my experience with the MammoSite, I have also worked with the Xoft Axxent™ ("Axxent"). In early 2007, I implanted the first five Axxent devices in the country.

15. I was also the first doctor to implant the Contura in one of my patients when the device became available in June 2007. Although I initially continued to use both the Contura and the MammoSite, I now use the Contura almost exclusively because of the benefits it offers over the MammoSite. In total, I have implanted the Contura in 35 patients. I paid $2,750.00 for the Contura devices I have used, the same price I paid for the MammoSite. SenoRx has never offered me a discount on this price.

16. I have also participated in the MammoSite registry study, and I serve on the National Advisory Board for Xoft Inc. I have invested $50,000 in SenoRx, and I own stock in Xoft.

PROBLEMS WITH BALLOON BRACHYTHERAPY GENERALLY

17. Although balloon brachytherapy offers many benefits over other available treatment options, there are some potential problems that doctors must consider. While the high dose rate radiation therapy offered by these devices allows for a greatly accelerated treatment time, doctors must be careful to limit the exposure of healthy tissue to this radiation.

18. Such radiation can be harmful to healthy tissue. If too much radiation reaches the skin, for example, it can burn the skin, leading to necrosis. When this happens, the affected area develops significant scarring, which is very difficult to heal. Similarly, if a critical dose of radiation reaches the ribs, it can kill the bone cells and/or lead to chronic rib pain, periosteal inflammation, or rib fracture. Radiation may also be harmful to the heart and lungs.

19. As a breast surgery oncologist, I am always looking to minimize or avoid these potential problems.

SUPERIORITY OF CONTURA OVER MAMMOSITE

20. When I first began using the Contura in my patients in June 2007, I did not know when I would use the MammoSite and when I would use the Contura. It quickly became clear to me that in almost every situation the Contura is preferable.

21. The benefits of the Contura lie in the flexibility its design offers over the MammoSite. The MammoSite only has one, central lumen. This means that it has a limited ability to produce a radiation profile that is not radially uniform. In contrast, the Contura has five lumens: one central lumen surrounded by four lumens that are offset in different directions from the center. By placing the radiation source in one of the offset lumens, a radiation oncologist can push or reduce the radiation profile in a particular direction. The flexibility this design offers is helpful in several ways.

22. First, the Contura's design allows a physician to reduce the radiation exposure of healthy tissue such as the skin and ribs. Because there is very limited ability to shape the radiation profile with the MammoSite, I do not feel comfortable using the device unless there is approximately 7 mm between the outer surface of the balloon and the skin surface ("skin bridge"). Otherwise, the risk is too great that there will be radiation damage to the skin. Balloon brachytherapy generally was a limited option for women with small breasts because of the difficulty obtaining a skin bridge of 7 mm. With the Contura, the radiation source can be placed in the offset lumen farthest away from the skin so that the dose of radiation at the skin's surface is lower. In fact, I have safely and effectively used the Contura in patients with skin bridges as small as 2 mm. I could never have used the MammoSite with those patients. Similarly, when

the lumpectomy cavity is too close to the ribs, the radiation source can be placed in the offset lumen farthest away from them as well. As a result, I have found in my practice that I can use the Contura with many patients who would not be candidates for the MammoSite given the skin bridge or proximity to the ribs. This greatly expands the treatment options for women who need such a device.

23. The Contura's multi-lumen design offers another advantage over the MammoSite: Because physicians can shape the dose to push it away from the skin or ribs, I have not had to abort treatment and remove the Contura from patients, as I have had to do many times with the MammoSite. It is difficult to know the exact distance of the skin bridge before implanting one of these devices and inflating the balloon. This is because when the balloon is inflated, it will slightly compress the tissue around the edge of the balloon. Many times I have estimated that the skin bridge will be sufficient for treatment with the MammoSite (*i.e.*, approximately 7 mm or greater), only to find out that there is more compression than expected once the device is implanted and the balloon inflated. When this happens, I have to remove the device from the patient and direct her to undergo six weeks of external beam irradiation. Needless to say, this is incredibly disruptive to patients who have undergone an invasive surgery only to find out that they cannot enjoy the benefits of balloon brachytherapy. Rather than being treated in five days, those patients must endure weeks of stress from radiation treatments as well as disruption to their career and family commitments. Since I began using the Contura, I have not had to pull one device because of a narrow skin bridge. Whenever the tissue compresses more than expected, the Contura's multiple lumens allow the radiation oncologist to shape the dose accordingly, and therefore avoid having to pull the device.

24. Finally, the Contura is a superior device even for many women I could have treated with the MammoSite. Its multi-lumen design allows the radiation dose to be pushed towards the location of the tumor to better target the cancerous cells left after a lumpectomy. When I perform a lumpectomy, I remove not only the tumor itself but an area of tissue that contains the tumor within it. The tumor is almost never located perfectly in the center of this removed tissue. Consequently, the cancerous cells remaining in the breast are not likely to be

evenly spread around the margin of the lumpectomy cavity. They are likely to be skewed in one direction or another depending on where the tumor was located in the removed tissue. With the MammoSite, there is a limited ability to correct for this. In contrast, the multi-lumen design of the Contura allows the radiation dose to be pushed in the direction of the tumor to better target the relevant tissue.

25. In sum, I believe that the Contura is superior to the MammoSite in its treatment of many patients. It is safer, more effective, and allows for the treatment of more women. I believe it represents the next generation of balloon brachytherapy devices.

CONTURA AND THE BALLOON BRACHYTHERAPY MARKET

26. I have been asked whether the Contura could tarnish medical opinion regarding balloon brachytherapy products and procedures or result in fewer women electing to undergo post-lumpectomy treatment with such products. My answer to both of these questions is no. To the contrary, I believe that the Contura will enhance medical opinion of balloon brachytherapy and increase the number of women who elect such treatment.

27. The Contura delivers the same dose from same source as MammoSite, but it allows doctors to shape that dose so it is safer and more targeted. In fact, the Contura's multi-lumen design decreases the chance that radiation will harm the skin or ribs. As a result, patients are left with better results and fewer negative events following the procedure. In addition, the chance that I will have to prematurely remove a device because of skin-bridge compression is significantly decreased or eliminated.

28. Far from tarnishing medical opinion about balloon brachytherapy, the Contura is actually creating interest and excitement around the procedure. Doctors are excited when they learn of the flexibility possible from treatment with the Contura. In my opinion, the availability of the Contura will expand the use of balloon brachytherapy following a lumpectomy.

29. I also believe that it is incorrect to say that the Contura is "untested," if for no other reason than that I have successfully used the device dozens of times. In my experience, the Contura has allowed me to treat patients I never could have treated with the MammoSite, and it

can produce better results than the MammoSite in other cases. I know doctors across the country who are having the same positive experience with the Contura.

30. I have been a strong supporter of balloon brachytherapy products and procedures for years. They have enormously benefited my patients, and I would not use a product that I thought was dangerous or untested. Nor would I use a device that I believed would discourage other doctors from using balloon brachytherapy because I believe that the procedure provides enormous benefits to patients.

31. I have also been asked about SenoRx's statement that "[s]ome patients who are presently candidates for balloon therapy are excluded because of the location of the lesion and their breast size. Contura's advanced multi-lumen design may address this issue for certain patients." SenoRx Press Release Announcing Contura's Launch (Jan. 17, 2008). Not only *may* the multi-lumen design address this issue, it *does* address it for many patients.

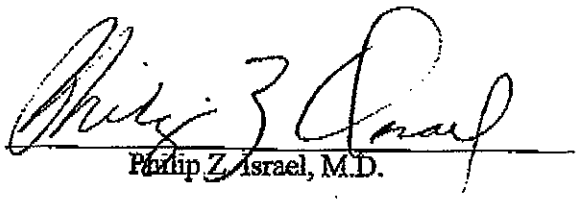
32. With the MammoSite, I sometimes had to exclude patients whose tumor was too close to the skin or ribs, in upper-inner breasts, inferior mammary fold, or under the nipple, as well as women with small breasts. Contura's multi-lumen design offers the ability to shape the radiation dose to treat many of these women.

33. Based on my experience with both devices, I would estimate that the Contura can treat between 20% and 30% more women than the MammoSite. This translates into a significant number of women who would not be able to enjoy the benefits of balloon brachytherapy if the Contura were not available.

34. As a clinician who has been closely involved with balloon brachytherapy for years, I can say without hesitation that the public interest would be harmed if the Contura is taken off the market. The Contura is an advanced product for treating a serious disease, and clinicians need this device. My patients would suffer an immediate setback if this product were not available to me.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: March 27, 2008



Philip Z. Israel, M.D.

Exhibit 1

Philip Z. Israel, M.D.

702 Canton Road
Marietta, Georgia 30060
(770) 428 4486

PERSONAL

Director, The Breast Center
Marietta, Georgia
Clinical Associate Professor,
Dept. of Surgery,
University of Tennessee College of Medicine,
Chattanooga Unit

EDUCATION AND TRAINING

Pre-Medical:
Emory University: 1954-1957
Atlanta, Georgia

Medical School:
Emory University School of Medicine
Atlanta, Georgia
1958-1961
M.D.

Internship:
Emory University
Atlanta, Georgia
General Surgery: 1961-1962

Residency:
Emory University Hospital
General Surgery
1962-1966

Includes rotation through the following hospitals:

Emory University Hospital
Atlanta, Georgia

Veterans Administration Hospital
Atlanta, Georgia

Grady Memorial Hospital
80 Butler Street
Atlanta, Georgia

WORK HISTORY

United States Air Force, Surgeon
Carswell AFB, Fort Worth, Texas 1966 – 1968

Dellinger, Israel & King, MD, PC
Smyrna, Georgia 1968 – 1986

The Breast Center
Marietta, Georgia 1986 - Present

SOCIETY MEMBERSHIPS

Fellow, American Society of General Surgeons
Fellow, American College of Surgeons
American Medical Association
Southern Medical Association
Cobb County Medical Society
Clinical Oncology Association of Georgia
Atlanta Medical Association
Fellow, Southeastern Surgical Congress
Member, American Society of Breast Surgeons
Society of Surgical Oncology
Board of Directors, American Society of General Surgeons
Member, Stereotactic National Faculty, American College of Surgeons

MEDICAL LICENSURE

Georgia License: #9527
DEA # AZ-1152189

BOARD CERTIFICATION

Diplomate American Board of Surgery 1967-Present

HOSPITAL STAFF POSITIONS

Kennestone Hospital: 1968-Present
677 Church Street
Marietta, Georgia 30060

Cobb Hospital and Medical Center: 1968-Present
3950 Austell Road
Austell, Georgia 30106

Emory Adventist Hospital: 1974-Present
3949 South Cobb Drive
Smyrna, Georgia 30080

Marietta Surgical Center: 1983-Present
796 Church Street
Marietta, Georgia 30060

HONORARIUMS AND APPOINTMENTS

State Chairman, Cancer Liaison Committee, American College of Surgeons: 1993-1999
Past President, Medical Staff: Cobb Hospital and Medical Center: 1970-1971
Past President, Medical Staff: Smyrna Hospital: 1975-1976
Past President, J.C. Thoroughman Surgical Society: 1965
Chairman, Nutritional Support Team, Kennestone Hospital
Past President, Cobb County Medical Society: 1976
Member, Executive Committee, Medical Alumni Association, Emory University 1992-1995
State Chairman, Committee on Cancer: American College of Surgeons
Medical Advisor, Kennestone Mammography Center: 1986-1991
President, The Breast Center, P.C. Marietta, Georgia
Medical Director, Breast Diagnostic Center, Marietta Surgical Center: 1991-Present
Member, National Consortium of Breast Centers
Member, Society for the Study of Breast Disease
Chairman of the Board, American Society of Breast Surgeons: 1998
Member, Committee on Stereotactic Breast Biopsy Accreditation, American College of Radiology
Member, Board of Directors, MM Insurance Company

PUBLICATIONS:

Stereotactic Needle Biopsy for Occult Breast Lesions: A Minimally Invasive Alternative, *The American Surgeon*, January 1995, 87-91.

A Comparative Analysis of Node Positive and Node Negative Stage II Breast Cancer. Kennestone Hospital, *Annual Tumor Journal Report*, June, 1995.

The Revolution in Breast Biopsy: Where is the Surgeon?, *The American Surgeon*, February, 1996, 93-95.

Core Needle Technology for Breast Biopsy: S. H. Parker, P. Z. Israel, *Surgical Technology International,* September 1996.

Stage II Breast Cancer: Survival Difference, Tumor Size vs. Lymph Node Status. *Cancer Committee Journal, Kennestone Hospital,* Annual Report, 1996.

Beyond the Credentialing and Privileging Controversy Surrounding Image-Guided Breast Biopsy. M. J. Edwards, P. Z. Israel, M.D., *Bulletin of the American College of Surgeons,* Volume 82, Number 6.

Commentary: Breast Diseases: *The Quarterly Yearbook* "Impact of Core Needle Breast Biopsy on the Surgical Management of Mammographic Abnormalities" September 2001.

Breast Cancer Quarterly
Ultrasound Core Biopsy:
Commentary. January 2002

A Prospective Study of the Removal of Imaged Breast Lesions by an 11- Gauge Vacuum Assisted Biopsy Probe System. R. E. Fine M.D., P.Z. Israel, M.D., *The American Journal of Surgery*, July 2001

A Prospective, Randomized, Multi-Center Clinical Trial To Evaluate the Safety and Effectiveness of the SenoRx Anchor Guide Lesion Localization Devise.

SPECIALITY PRESENTATIONS
Philip Z. Israel, M.D.
Director, The Breast Center
Marietta, Georgia

January 20-25, 1996	Breast Care in the 21st Century	Key Largo, Florida
January 27-30, 1996	Fourteenth International Breast Cancer Conference	Miami, Florida
February 4, 1996	Southeastern Surgical Society Minimally Invasive Surgery, Breast	Tampa, Florida

February 8, 1996	Breast Cancer, Medical Mal-Practice Conference-Risk Management for Breast Care	Scottsdale, Arizona
April 12, 1996	Percutaneous Image Guided Breast Biopsy American Society of General Surgeons	New York, New York
April 13, 1996	Ultrasound and Stereotactic Guided Needle Core Biopsy American College of Surgeons Annual Spring Meeting	New York, New York
April 19, 1996	Breast Ultrasound for the Surgeon	Santa Fe, New Mexico
July 13, 1996	Stereotactic Needle Core Biopsy Columbia HCA Surgical Center	Miami, Florida
August 15, 1996	Percutaneous Image Guided Breast Biopsy Florida Surgical Society	Captiva Island, Florida
September 13, 1996	Medical Malpractice-Defense Attorney, Breast Cancer Seminar	Jacksonville, Florida
October 6, 1996	The Surgeons' Role in Minimally Invasive Biopsy American College of Surgeon Clinical Congress	San Francisco, California
November 11, 1996	Needle Core Breast Biopsy and the Surgeon North Georgia Chapter American Cancer Society	Charlotte, North Carolina
November 26, 1996	American College of Surgeons Task Force, Stereotactic Needle Core Biopsy, FDA.	Washington, DC
January 17 & 18, 1997	Louisiana Chapter, American College of Surgeons "New Innovations in Breast Care" Stereotactic Breast Biopsy	New Orleans, Louisiana
February 2, 1997	Image Guided Breast Biopsy Southeastern Surgical Congress	Nashville, Tennessee

March 13, 1997	Georgia Chapter American College of Surgeons Report, State Chairman Cancer Liaison	Cloister Hotel St. Simon's Island, Georgia
April 5 & 6, 1997	American College of Surgeons Image Guided Percutaneous Biopsy	Wyndham Hotel San Diego, California
May 3, 1997	Institute for Advanced Imaging Imaging for Breast Cancer "A Surgeon's Approach for Image Guided Breast Biopsy"	Adolphus Hotel Dallas, Texas
June 27, 1997	American College of Surgeons Percutaneous Breast Biopsy for Surgeons Mammography Interpretation for Surgeon	Chicago, Illinois
September 22-27, 1997	Breast Care in the 21st Century Steve Parker – Director "Abnormal Mammogram, When to Monitor?" "Risk Management for Mammographers" "Biology of Breast Cancer"	LaCosta Resort Carlsbad, California
September 27, 1997	Medical Physicist Institute "Clinical Use of Breast Imaging by Surgeons"	Atlanta, Georgia
October 13-20, 1997	American College of Surgeons Clinical Congress Stereotactic and Ultrasound Workshop Live Stereotactic Telesurgery "Imaging for Surgeons"	Chicago, Illinois
October 12, 1997	The World Foundation for Medical Statistics in Female Health "New Methods in Breast Cancer Detection"	Key Biscayne, Florida
October 28, 1997	MQSA Committee, FDA Task Force for ACS Presentation to FDA Panel "Surgical Participation in Image Guided Breast Biopsy"	Washington, DC

November 4, 1997	Milwaukee Surgical Society "Image Guided Breast Biopsy: The Surgeons Role"	University Club Milwaukee, Wisconsin
November 21 & 22, 1997	Arizona Chapter American College of Surgeons "Breast Imaging for Surgeons"	The Camelback Resort Scottsdale, Arizona
February 11 & 12, 1999	4th Annual Multidisciplinary Symposium on Breast Disease "Stereotactic Biopsy- Role and Limitations"	The Ritz Carlton Amelia Island, Florida
September 16, 1999	Overland Park Regional Medical Center, "Image Guided Breast Biopsy"	Medical Center Overland Park, Kansas
October 11 – 15, 1999	Fall Meeting American College of Surgeons "Introduction to Stereotactic Breast Biopsy" Moderator and Director	San Francisco, California
October 11 – 15, 1999	Fall Meeting American College of Surgeons Post Graduate Course #8, Breast Cancer, "Stereotactic Breast Biopsy"	San Francisco, California
October 23, 1999	International Institute for Continuing Medical Education "The Breast Biopsy: Before, During and After"	Hotel Inter-Continental, New Orleans, Louisiana
February 3, 2000	Southeastern Surgical Congress Postgraduate Course, Faculty	Orlando, Florida
March 3, 2000	Annual Meeting & Scientific Program, American Society of General Surgeons, Faculty	Hilton Resort, Orlando, Florida
April 30, 2000	Spring Meeting, American College of Surgeons, Faculty	Washington, DC
August 4, 2000	"Breast Cancer for the General Surgeon", Faculty	Ritz Carlton Atlanta, Georgia
October 21, 2000	Annual Meeting, American College of Surgeons, Faculty	Chicago, Illinois

November 4, 2000	Commission on Cancer Annual Meeting, American College of Surgeons, Faculty	Chicago, Illinois
February 5, 2001	New Breast Biopsy Instruments	Vail, Colorado
March 19, 2001	Radiology Imaging Associates "Breast Imaging & Intervention in the 21st Century"	Amelia Island Plantation, Amelia Island, Florida
April 20, 2001	American Society of General Surgeons Meeting	Toronto, Canada
April 22, 2001	Spring Meeting, American College of Surgeons, Faculty	Toronto, Canada
April 28, 2001	American Society of Breast Surgeons Meeting, Faculty	San Diego, California
October 14, 2001	Fall Meeting, American College Of Surgeons, "Mammogram Interpretation for Surgeons"	New Orleans, Louisiana
October 16, 2001	Fall Meeting, American College Of Surgeons, "Stereotactic Breast Biopsy"	New Orleans, Louisiana
February 1, 2002	10th Annual Advanced Laparoscopy Symposium, "Biology of Breast Cancer" "Mammography for Surgeons" "New Breast Biopsy Technology" "Stereotactic & Ultrasound Breast Biopsy"	Vail, Colorado
April 14, 2002	American College of Surgeons Spring Meeting, Mammogram Interpretation, Stereotactic Breast Biopsy, "Stereotactic, Mammogram & Ultrasound, Putting it all Together", Faculty, Ultrasound Workshop	San Diego, California
April 27, 2002	American Society of Breast Surgeons Spring Meeting, Faculty, Ultrasound Workshop, Medical Malpractice Issues	Boston, Massachusetts

May 11, 2002	"The Surgeon as a Breast Clinician, "The Surgeon & Mammographic Analysis"	Las Vegas, Nevada
June 6, 2002	Annual Meeting, Colorado Chapter American College of Surgeons "Medical Liability & a Different View of Breast Cancer Biology"	Breckenridge, Colorado
June 7, 2002	Annual Meeting, Colorado Chapter American College of Surgeons "New Breast Biopsy Technologies"	Breckenridge Colorado
September 21, 2002	Georgia OB-GYN Society Meeting "The Obstetrician & Breast Care"	Reynold's Plantation Greensboro, Georgia
September 28, 2002	Ultrasound for the General Surgeon	Hyatt Regency Atlanta, Georgia
October 6, 2002	Fall Meeting, American College Of Surgeons, Moderator & Introduction	Hilton Hotel San Francisco, California
October 6, 2002	Fall Meeting, American College Of Surgeons, "The Abnormal Mammogram: Breast Imaging & Data System (BI-RADS) Classification	Hilton Hotel San Francisco, California
October 6, 2002	Fall Meeting, American College Of Surgeons, "Stereotactic Biopsy Techniques: Overview"	Hilton Hotel San Francisco, California
October 9, 2002	Fall Meeting, American College Of Surgeons, "Putting it all Together"	Hilton Hotel San Francisco, California
January 18, 2003	19th Annual Breast Symposium S.E. Plastic Surgical Society, "New Technology in Breast Cancer Diagnosis"	Hyatt Hotel Atlanta, Georgia
February 8, 2003	Brachytherapy Breast Radiation Conference, "Mammosite Catheter Experience"	Miami, Florida

February 9, 2003	Advanced Laproscopic Surgical Techniques, "Mammography for Surgeons" "Breast Cancer Biology" "New Technology in the Breast Cancer Diagnosis"	Sonnenalp Hotel Vail, Colorado
April 31, 2003	American Society of Breast Surgeons Spring Meeting, "Biology of Breast Cancer"	Hyatt Hotel Atlanta, GA
May 7, 2003	OB-GYN Grand Rounds, Grady Memorial Hospital, "Breast Disease Evaluation"	Atlanta, GA
May 9, 2003	ZOFT Corp. "Structuring Clinical Trials for PBI"	Fremont, CA
May 20, 2003	Presentation OB Dept. of Northside Hospital, "Breast Examination and Follow-up"	Atlanta, GA
July 31, 2003	Grand Rounds, U.T. Chattanooga, "Indications & Use of Mammosite Catheter"	Chattanooga, TN
August 8, 2003	Presentation, Kennestone Hospital, Tumor Board, "Indications for Partial Breast Irradiation/Mammosite Catheter"	Marietta, GA
October 19, 2003	American College of Surgeons Fall Meeting, "Mammographic Interpretation for Surgeons", "Case Management of Difficult Breast Cancer Presentation"	Chicago, IL
November 6, 2003	City of Atlanta, AORN Conference "New Devices for Breast Biopsy"	Atlanta, GA
January 17, 2004	20th Annual Breast Plastic Surgery Symposium, "New Technologies In Breast Biopsies"	Grand Hyatt Hotel Atlanta, GA
January 28 – 31, 2004	Annual Phoenix Surgery Symposium, "The use of the Mammosite Catheter", "Breast Cancer Biology", New Breast Biopsy Devices"	Scottsdale Hilton Scottsdale, AZ

February 8 – 11, 2004	12th Annual Rocky Mountain Laproscopic Symposium, The Surgeon & Partial Breast Radiation", New Biopsy Instruments for Breast Cancer Diagnosis", "Breast Cancer Growth & Development", Ultrasound Breast Biopsy"	Sonnenalp Hotel Vail, CO
February 25 – 28, 2004	Miami Cancer Conference, "New Percutaneous Biopsy Devices" "Techniques to Create a Margin Free Lumpectomy for Cancer"	Miami, Florida
March 31 – April 4, 2004	American Society of Breast Surgeons, "Mammography & The Surgeon; The Selection Process", "Basic Breast Ultrasound For the Surgeon Workshop", Integrated Diagnostic & Interventional Ultrasound Workshop"	Las Vegas, Nevada
May 24 – 27, 2004	American College of Surgeons Spring Meeting, "Mammography Interpretation for Surgeons" Case Presentation with Dr. Chris Murphy	Boston, Massachusetts
September 11, 2004	Georgia OB-NET Organization "The Primary Care Physician & The Diagnosis of Breast Cancer"	Technology Global Center Atlanta, Georgia
October 10-14, 2004	American College of Surgeons Fall Meeting, "Basic Mammography for Surgeons" "New Techniques for Breast Biopsy" "Advanced Mammographic Interpretation for Surgeons" "Breast Cancer and Liability Exposure"	New Orleans, Louisiana
December 9-12, 2004	Albert Einstein College of Medicine 21st Annual Controversies and Techniques in Medicine "Techniques for successful Lumpectomy" "New percutaneous biopsy devices"	Sherridan Hotel New York City

February 6-9, 2005	13th Annual Rocky Mountain Advanced Surgical Symposium "Ultrasound interpretation for the surgeon" "Achieving clear margins with lumpectomy" "Localized breast irradiation; the surgeons role" "Breast cancer biology" "Breast cancer litigation"	Vail, Colorado
February 26-March 3, 2005	The Breast Course "The Art of Successful Lumpectomy" "Surgical Treatment of DCIS" "Image Guided Biopsy"	Quebec City
March 15-20, 2005	American College of Surgeons Annual Meeting "Mammogram Interpretation for Surgeons" "Medical Practice Applications" "Performing a Successful Lumpectomy	Los Angeles, Ca.
October, 2005	American College of Surgeons Fall Meeting "Incorporating Stereotactic Breast Biopsy into A General Surgery Practice" "Mammogram Interpretation for the Surgeon" "Advanced Mammogram Interpretation"	San Francisco, Ca.
December 07, 2005	American College of Surgeons	
February 22, 2006	Participant, Best Practices Group "Partial Breast Irradiation"	Miami, Florida
February 23, 2006	American College of Radiation Oncology "The Surgeons Role in Partial Breast Irradiation"	Orlando, Florida
March 12-16, 2006	The Breast Course "Surgical Options for Breast Cancer" "The Surgeons Perspective of Neo-adjuvant Chemotherapy" "Surgical Options for DCIS" "Conservative Versus Non-conservative Surgery for Invasive Breast Cancer" "The Biology of Breast Cancer" "Risk Management Issues for Mammographers" "Mammosite Catheter Implantation for Partial Breast Irradiation"	Key Largo, Florida

April 6, 2006	American Society of Breast Surgeons Participant, Genomic Health, Oncotype Dx Speaker Training Program	Baltimore, Md.
July 08, 2006	Mammographers Society of Georgia New Techniques in Breast Cancer Diagnosis	Atlanta, Ga
February 02-04, 2007	Breast Imaging, Intervention & Innovations Intercontinental Hotel Presentation; "Lumpectomy for Breast Cancer, Obtaining Clear Marging" Presentation: "Partial Breast Irradiation with Mamosite Catheter"	Atlanta, Ga
February 04-07, 2007	14th Annual Rocky Mountain Advanced Surgical Symposium Advanced Laproscopic Procedures Presentation: "Breast Cancer Liability" "Selecting Proper Operation for Breast Cancer"	Vail, Colorado
March 12-15, 2007	The Breast Course 2007 Breast Diseases: Detection, Intervention and Therapy "Updates In Breast Cancer Surgery" "Malpractice Liability For Mammographer" "Sentinel Lymph Node Issues and Options" "Breast Cancer Biology: Is the outcome predetermined?" "Surgical Perspective On Neoadjuvant Chemotherapy" "Electronic Brachytherapy" "Conservative Vs Non-conservative Surgery"	Key Largo, Florida
May 05, 2007	American Society of Breast Surgeons Eighth Annual Meeting "Breakfast Symposium On accelerated Partial Breast Irradiation" Presentation: "Early Clinical Results of Patients Treated With The Axxent Electronic Brachytherapy System"	Phoenix, AZ
September 15, 2007	American College of Surgeons 4th District Annual Meeting "Breast Evaluation for the Gynecologist"	Chicago, IL
September 22, 2007	SenoRx Investigators Meeting "Experience with the Multi-Lumen APBI Catheter"	Chicago, IL
October 07, 2007	American College of Surgeons	New Orleans, LA

Annual Fall Meeting
"Basic Mammographic Skills for the General Surgeon"

October 07, 2007	American College of Surgeons Annual Fall Meeting "Advanced Mammographic Interpretation"	New Orleans, LA
October 08, 2007	American College of Surgeons Annual Fall Meeting "Experience with Implantation of the Contura APBI Catheter"	New Orleans, LA
October 09, 2007	American College of Surgeons Annual Fall Meeting "Stereotactic Breast Biopsy Workshop"	New Orleans, LA
October 09, 2007	American College of Surgeons Annual Fall Meeting "Minimally Invasive Breast Biopsy"	New Orleans, LA
October 10, 2007	American College of Surgeons "Breast Ultrasound for the Surgeon" Commission on Cancer	New Orleans, LA
January 24, 2008	"Breast Cancer Diagnosis and Treatment" Cobb Hospital and Medical Center	Austell, GA

STEREOTACTIC NEEDLE CORE BIOPSY TRAINING, MARIETTA

Sponsored by: The Breast Center, Marietta
Georgia Division, The American Cancer Society
Didactic and Hands on Training for Stereotactic Breast Biopsy
Faculty Instructor and Lecturer

June 1992	November 1994	March 30, 1996
September 1993	January 1995	May 1996
December 1993	February 1995	June 1996
January 1993	April 1995	August 1996
February 1993	May 1995	December 1996
April 1993	June 3, 1995	March 1997
May 1993	June 10, 1995	
June 1993	July 1995	
October 1993	October 1995	
December 1993	February 3, 1996	
June 1994	February 10, 1996	
July 1994	March 9, 1996	
September 1994	March 16, 1996	

BREAST ULTRASOUND FOR THE SURGEON-INSTRUCTOR & LECTURER

Sponsored by: The Breast Center, Marietta, Georgia
Georgia Division, The American Cancer Society

March 1, 1997	Sheraton Suites	Atlanta, Georgia
December 14, 1996	Crowne Plaza	New York, New York
December 7, 1996	Renaissance Waverly	Atlanta, Georgia
August 24, 1996	Renaissance Waverly	Atlanta, Georgia
June 22, 1998	The Bostonian	Boston, MA
May 18, 1996	Hyatt Suites	Marietta, Georgia

March 9, 1996	Hyatt Suites	Marietta, Georgia
October 28, 1995	Hyatt Suites	Marietta, Georgia
December 9, 1995	Doubletree	Atlanta, Georgia

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On March 28, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF PHILIP Z. ISRAEL, M.D. IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on March 28, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Counterdefendants.

Case No. 08-CV-0133 RMW

DECLARATION OF COLIN G. ORTON, PH.D. IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Date: April 21, 2008
Time: 2:00 p.m.
Courtroom: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

I, Colin G. Orton, Ph.D., declare that:

BACKGROUND

1. The facts set forth below in this declaration are based on my personal knowledge, and if called as a witness, I could and would testify competently to those facts.

2. I am a radiation physicist with over three decades of experience specializing in medical radiation physics and, in particular, brachytherapy.

3. My educational and professional history are summarized in my C.V., attached as Exhibit 1 hereto. In summary, I graduated from the University of Bristol (UK) in 1959 with a Bachelor of Science degree in Physics. I subsequently obtained a Masters' degree (1961) and Ph.D. (1965) in Radiation Physics from St. Bart's Hospital Medical College, London University.

4. From 1966 through 1975, I practiced as a Medical Radiation Physicist at NYU Medical Center, including serving as Chief Physicist and Assistant and Associate Professor of Radiology. From 1975 through 1981 I served as the Chief Physicist at Rhode Island Hospital, and an Associate Professor of Radiation Medicine at Brown University. From 1981 through my retirement in 2003, I was the Chief Physicist and a Professor of Radiation Oncology at Harper Hospital and Wayne State University in Detroit, Michigan.

5. I am a member of several professional societies related to medical radiation physics, including the American Association of Physicists in Medicine ("AAPM") and American Brachytherapy Society ("ABS"). I served as president of AAPM in 1981 and in 1993 I was honored to be awarded the William D. Coolidge Award by the AAPM. The Coolidge Award is AAPM's highest honor, and is presented to a member who has exhibited a distinguished career in medical physics, and who has exerted a significant impact on the practice of medical physics. In addition I was president of the American College of Medical Physics ("ACMP") in 1985, and received the Marvin M. D. Williams Award from the ACMP, their highest award. In 2002, I served as President of ABS, and prior to that, in 1995, I received ABS's highest honor, the Ulrich Henschke Award.

6. I have never testified as an expert in a patent case, and have not testified in any other matter, as an expert or otherwise, in the last four years.

7. I am being compensated for my time in this matter at my usual rate of $450 per hour plus expenses. My compensation does not depend on the outcome of this litigation.

8. For purposes of the opinions set forth herein, I have considered United States Patent No. 5,931,774 (the "'774 patent") and a 1990 article entitled "A New Technique of Brachytherapy for Malignant Gliomas with Caesium-137: A New Method Utilizing a Remote Afterloading System," authored by Ashpole, *et al.* ("Ashpole"). Although I did not consider them for purposes of this opinion, I also have been provided and have reviewed the three patents that I have been told are at issue in this suit: the '813 patent, the '204 patent, and the '142 patent.

PERSON OF ORDINARY SKILL IN THE ART

9. I have been asked to discuss certain references from the perspective of a "person of ordinary skill in the art." For purposes of my opinions as set forth herein, I have been told to assume the following: "The relevant scientific area is radiation oncology physics, with a focus on brachytherapy. Typically, individuals of ordinary skill in this field would hold a M.S. degree in Physics or Engineering, with 3 or more years of clinical medical physics experience; or a Ph.D. degree in Physics or Medical physics with 2 or more years of clinical experience. Such a person would have a broad knowledge of the physics of brachytherapy procedures, of the principles of radioactivity and an understanding of the effect of radiation on cells. In addition, such a person would have an understanding of other means of treating cancer cells with radiation such as with an external, gantry-mounted linear accelerator. Individuals with such qualifications are considered eligible for certification as a radiation oncology physicist and considered capable of working independently in a clinical environment as a medical physicist."

10. I have not been asked to form, and have not formed, any opinions as to whether this definition is correct.

THE DISCLOSURE OF THE ASHPOLE ARTICLE

11. I have been asked to discuss, from the viewpoint of a person of ordinary skill in the art, the disclosure of a 1990 article entitled "A New Technique of Brachytherapy for Malignant Gliomas with Caesium-137: A New Method Utilizing a Remote Afterloading

System," authored by Ashpole et al. (attached as Ex. 5 to the Declaration of Aaron P. Maurer) ("Ashpole").

12. Ashpole describes the irradiation of a site from which a brain tumor has been removed, using a modified endotracheal tube. The modified endotracheal tube consists of a catheter which has at least one lumen, which was meant to serve as an airway in the unmodified device. There is a balloon at the far end of the catheter.

13. The catheter's lumen extends to, and through the balloon. The balloon surrounds the lumen at the end of the device. The endotracheal tube's lumen is "sealed off" at the end of the balloon. See pp. 334 & Figure 1 below.

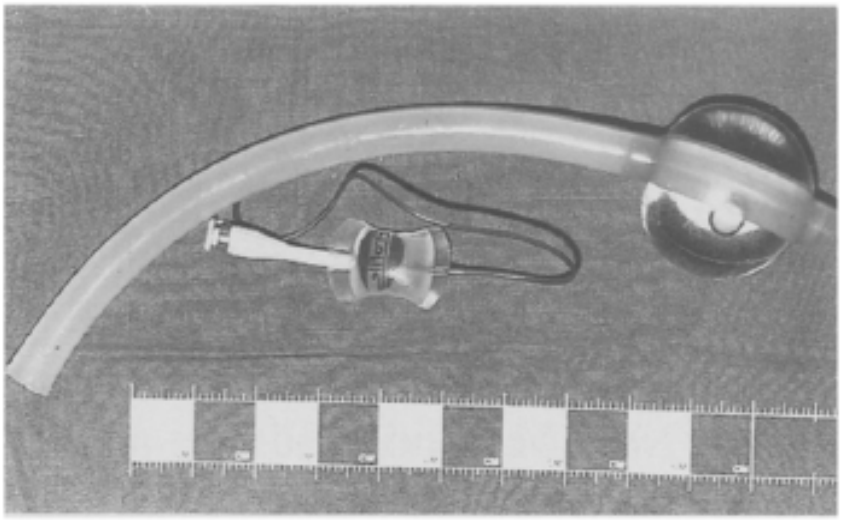


Fig. 1. The modified catheter with the sealed distal end and inflated balloon.

14. After a patient underwent surgery to remove "as much tumour . . . as deemed safe," the modified catheter was inserted into the "postsurgical cavity." See pp. 334.

15. A person of ordinary skill in the art would understand the catheter portion of the modified endotracheal tube to have two ends. The end portion of the catheter that extends into the balloon would be referred to as the "distal," or far end, as it is farthest away from the physician. The end nearest the physician would be referred to as the "proximal," or near, end.

16. "The balloon" portion of the device then "was filled with radio-opaque contrast medium." This fluid is not radioactive, but instead is an inert fluid meant that shows up in X-ray

images, and is intended to "facilitate later X-ray visualization and dosimetry calculations." See pp. 334.

17. The patient was transferred to a radiotherapy center, where a radiation afterloader made by the Selectron company was located. See pp. 334-35. An afterloader is a machine in which radioactive sources are stored for use in medical treatment. The radioactive sources inside of the Selectron afterloader used in Ashpole took the form of "active and inactive spherical pellets" of Caesium-137.

18. The "applicator" portion of the Selectron (i.e., the portion of the device into which its radioactive beads are loaded for treatment) was "manually fitted into the protruding intracranial applicator ensuring that the tip [of the Selectron applicator] was right down to the base." See pp. 335. A person of ordinary skill in the art would understand this to mean that the Selectron applicator was inserted into the proximal end of the modified endotracheal tube, and was seated such that the tip Selectron applicator extended to the distal end of the modified endotracheal tube.

19. A "dummy source train" was positioned in the Selectron applicator, and radiographs (essentially X-ray pictures) of the applicator in place in the patient's skull were taken in order to assist in calculating the source configuration required to deliver the prescribed dose and dose distribution. One such radiograph is reproduced in Figure 3. See pp. 335, and Figure 3.

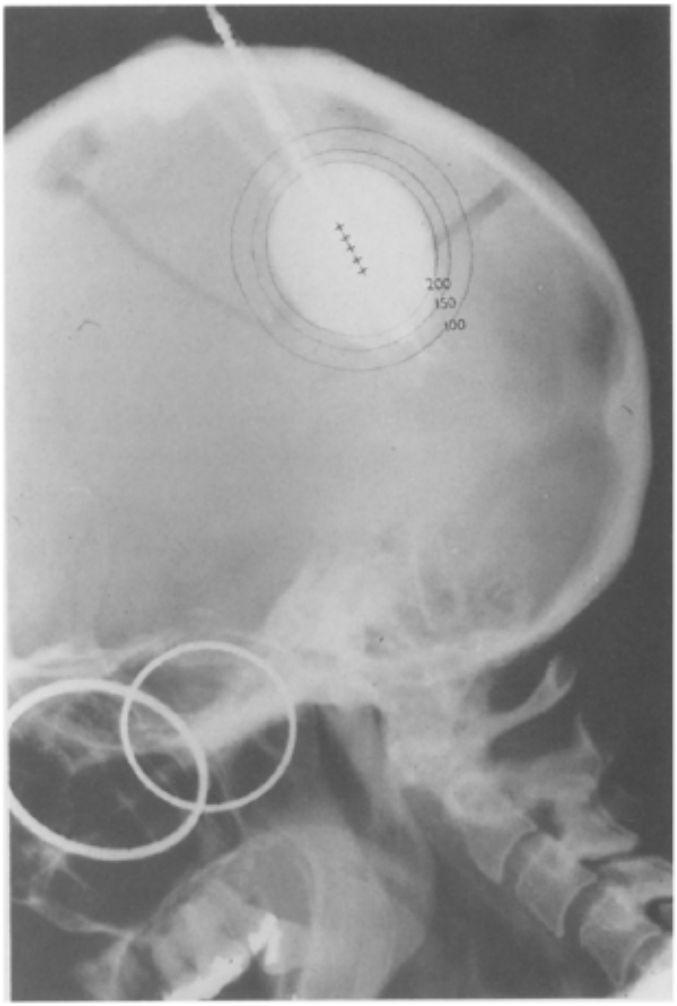


Fig. 3. Lateral radiograph showing the double ring method of magnification calculation, and Isodose curves computed around a dummy source train in the balloon.

20. The authors of Ashpole "aim[ed] to produce a mean dose rate of about 250 cGy/h at a distance of 0.5 cm from the balloon's surface for a total of about 20 h to give a total dosage of 50 Gy to the tumour bed." See pp. 335. The abbreviation "Gy" refers to a Gray, a measure of radiation.

21. The required dose distribution was obtained by "varying the position of active and inactive beads in the source train until a satisfactory isodose curve to match the cavity shape is found." See pp. 335.

22. After the dose was calculated, and the dummy source train removed, "the patient [was] connected to the machine via a treatment tube and the Selectron programmed to deliver the

required dose." See pp. 335. That is, the dummy sources were removed and the active source train (consisting of the combination of active and inactive beads) was inserted into the distal end of the lumen inside the balloon for purposes of treatment.

23. According to Ashpole, several treatments were given, usually3-4 hours at a time, over 48 hours in order to achieve the target dose. See pp. 335.

24. After completion of the course of radiation, "the balloon is deflated, the tube removed and the skin closed under local anaesthetic." See pp. 336.

25. In the "Discussion" section of the article, the authors note that the dose distribution can be adjusted if need be, by varying the radioactive sources. "Postimplantation adjustment of the radioactive sources becomes easy with the remote control and pneumatic transfer system of the Selectron machine . . . . A certain measure of dosimetrical versatility is possible in that the positions of the active beads can be changed to produce an isodose distribution specific to the geometry of the individual tumour beds."

26. The authors state that target dose of 50 Gy was at 0.5 cm from the surface of the balloon was chosen since it "is of the same order of magnitude as that used by others" in delivering radiation to the brain tissue. It "takes into account the known tolerance of normal brain [tissue], the previously administered external beam radiotherapy and the remaining rim of tumour tissue." See pp. 336.

27. The authors further disclose that "The configuration of the balloon plays a key role in producing an acceptable dose distribution. . . . The balloon also acts as a buffer that absorbs the unacceptably high doses close to the sources and has a mechanical function in that it anchors the tube and acts as a stabilizer." See pp. 336. A person of ordinary skill in the art would understand the authors' statement to mean that the balloon spaces the radioactive sources at a sufficient distance from the normal tissues such that the high doses close to the radioactive sources are not delivered to the normal tissues.

28. A person of ordinary skill in the art would understand the authors' statements as discussed in paragraphs 26 and 27 to mean that the authors chose the dose used in order to provide a therapeutic effect to a target tissue, the target tissue being defined between the balloon

surface and 0.5 cm out from the balloon surface, while at the same time reducing or preventing necrosis (tissue death) in healthy brain tissue proximate the balloon surface.

29. A person of ordinary skill in the art would understand the authors statements as discussed in paragraph 25 and paragraph 27 to mean that the configuration of either the spherical radioactive beads and/or the balloon can be varied in order to provide dosing that meets the physician's dosimetric goals of providing treatment to the target tissue while reducing or preventing necrosis in healthy tissue proximate the balloon.

THE DISCLOSURE OF U.S. PATENT NO. 5,931,774

30. I have been asked to discuss, from the viewpoint of a person of ordinary skill in the art, the disclosure of U.S. Patent No. 5,931,774 to Williams, et al. (attached as Ex. 13 to the Declaration of Aaron P. Maurer) (the "'774 patent").

31. The '774 patent is entitled "Inflatable Devices For Tumor Treatment." See Patent Title.

32. The '774 patent describes "implantable devices for treatment of proliferative disorders," see Abstract, including "tumors." Col. 1:27-30.

33. There are a number of different devices, and variations of those devices, described in the '774 patent. One of those embodiments is pictured in Figure 3.

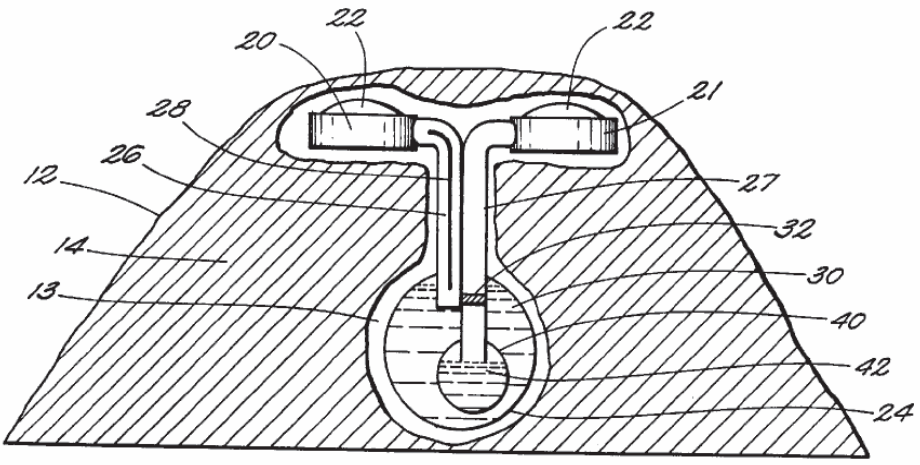


FIG. 3

34. The '774 patent states that, in certain embodiments, "the balloon is adapted for placement in a cavity left by surgical removal of a tumor from the patient." A person would understand the embodiment of Figure 3 to be one such embodiment, based on the drawing of the device's placement in a cavity.

35. The device of Figure 3 is a "double-balloon device." See col. 8:54-55.

36. The device of Figure 3 has two balloons: an "outer balloon" (labeled with number 24); and an "inner balloon" (labeled with number 40). See col. 8:57-59.

37. The outer balloon shown in Figure 3, by virtue of being a "balloon," has an expandable outer surface. See col. 8:1-5 ("In general, the balloon should have a small profile, e.g., a small size, when deflated, to permit facile placement in the patient's body and to minimize the size of a surgical incision needed to place the balloon at the desired site of action.")

38. Figure 3 shows "two treatment fluid receptacles," labeled with numbers 20 and 21. See col. 8:55-56.

39. Receptacle 20 "is fluidly connected to outer balloon 24 through catheter 26." See 8:57-58.

40. Receptacle 21 "is fluidly connected to inner balloon 40 by catheter 27." See 8:59-60.

41. The patent states that "The device of Figure 3 is useful where a chemotherapeutic fluid 30 is used to inflate the outer balloon 24, while a radioactive fluid 42 fills the inner balloon 40."

42. The patent states, and a person of ordinary skill in the art would understand, that radioactive fluids like fluid 42 in Figure 3 are "suitable for radiation therapy (brachytherapy)." See col. 3:25-26.

43. A person of ordinary skill in the art would understand the '774 patent to teach that the radiation therapy provided by radioactive fluid 42 would be used to treat the tissue surrounding the surgically-created cavity shown in Figure 3.

44. The '774 patent states that "In general, it is preferable that the balloon have a shape that permits the balloon to conform to the body cavity or lumen in which the balloon is to

be inflated. For example, a generally spherical cavity can be filled with a substantially spherical balloon." See col. 7:41-45. The patent further states that "In certain embodiments, a balloon will be selected such that, upon inflation, the balloon does not compress the tissue which is being treated, or surrounding tissues. Thus, when a radioactive treatment fluid is introduced into the device, e.g., by injection, the inflatable treatment device is inflated to a volume not substantially greater than a volume of the body cavity in which the device has been placed, thereby avoiding any substantial compression or distortion of normal tissue. For example, in one embodiment, when the balloon is placed within a cavity left by surgical removal of tissue, the balloon is not inflated to a size substantially larger than the size of the cavity." See col. 7:48-60.

45. A person of ordinary skill would understand the statements in paragraph 44 to mean that the outer balloon is configured so as to expand to conform to the void created by the surgical extraction of diseased tissue and thus to define an inner boundary of the tissue to be treated. The device in Figure 3 would be understood by a person of ordinary skill in the art to correspond to this description because, a person of ordinary skill would understand that it is important to have the outer balloon in contact with the tissue in order to keep the device in a constant position in the cavity, so that the radiation dose to be delivered can be calculated with precision.

46. At the point in time when "a radioactive fluid 42 fills the inner balloon 40," the device of Figure 3 would be understood by a person of ordinary skill in the art to have a radiation source located within the expandable outer surface (i.e., outer balloon) of the device. As shown in Figure 3, the inner balloon is not touching the outer balloon when it is filled with radioactive fluid.

47. A person of ordinary skill in the art would understand that the radiation source (i.e., the inner balloon filled with radioactive fluid) of the device of Figure 3 is asymmetrically located within the outer balloon, because the inner balloon is not located at the center of the outer balloon.

48. A person of ordinary skill in the art further would understand that the radioactive treatment fluid disposed in the inner balloon would provide isodose curves that approximate the shape of the inner balloon and which are centered around that inner balloon.

49. As the inner balloon is asymmetrically located within the outer balloon, the isodose curves corresponding to the radiation dose provided by the radioactive fluid inside the inner balloon would be asymmetric (i.e., not centered) with respect to the outer balloon. (An isodose curve is a 3-dimensional surface around a radioactive source that defines a constant dose level.)

50. A person of ordinary skill in the art would understand that, before the device shown in Figure 3 was used for therapeutic treatment of a patient via insertion of a radioactive fluid in the inner balloon, a radiation oncologist or radiation physicist necessarily would have calculated the dose (and isodose profile) that would be generated by the device. It was true well prior to the 1990s that no physician would use a radioactive source to treat a patient without such a dose calculation.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: March 27th, 2008

Colin G. Orton, Ph.D.

Exhibit 1

FACULTY MEMBER: Colin G. Orton

FACULTY APPOINTMENT: Professor Emeritus, Wayne State University

EMPLOYMENT HISTORY:

1959 - 1966 Research Physicist and Instructor, St. Bartholomew's Hospital Medical College, London

1966 - 1975 Chief Physicist, Assist. (66-71), Assoc. (71-75) Prof., NYU Medical Center, New York, NY

1975 - 1981 Chief Physicist, Rhode Island Hosp., Assoc. Prof., Brown Univ., R.I.

1981 - 2003 Chief Physicist, Prof., Radiation Oncology, Harper Hospital and Wayne State University, Detroit, MI.

EDUCATION:

University of Bristol, (UK)	BSc (Hons)	1959	Physics
St. Barts Hosp. Med. Coll., London Univ. (UK)	MSc	1961	Radiation Physics
St. Barts Hosp. Med. Coll., London Univ. (UK)	PhD	1965	Radiation Physics

CERTIFICATIONS:

ABR (Therapeutic Radiological Physics) : 1983

ABMP (Radiation Oncology Physics) : 1989

RESEARCH INTERESTS:

Bioeffect dose modelling and applications, HDR vs LDR comparison, cervix cancer patters-of-care, intraoperative HDR brachytherapy, single fraction radiotherapy, radiobiological aspects of neutron therapy, modified fractionation, volume effects, optimization, lung corrections.

RECENT SELECTED PUBLICATIONS (students highlighted):

Orton, C.G. "Dose Rate Considerations in Brachytherapy: Biological Equivalence of LDR and HDR." Journal of Medical Physics 19, 1-8, 1994.

Orton, C.G. "Single Fraction Treatment in Sterotactic Radiosurgery." Thai Cancer Journal, 19, 35-41, 1994.

Orton, C.G., **Somnay, A.** "Results of an International Review of Patterns of Care in Cancer of the Cervix." In: Brachytherapy from Radium to Optimization, Eds. Mould, R.F., Battermann, J.J., Martinez, A.A., Speiser, B.L. Nucletron, The Netherlands, 1994, pp. 49-54.

Orton, C.G. "Uses of Therapeutic X-Rays in Medicine." Health Physics, 69(5):662-676, 1995.

Orton, C.G. "Width of the Therapeutic Window: What is the Optimal Dose-per-Fraction for High Dose Rate Cervix Cancer Brachytherapy." Int. J. Radiat. Oncol. Biol. Phys. 31, 1011-1013, 1995.

Orton, C.G. "Comparison Between High Dose Rate and Low Dose Rate Brachytherapy." Ulusal Medikol Fizik Kongresi, Bayrak Yayimeilik, Istanbul, 17-32, 1996.

Orton, C.G. "Recent Developments in Time-Dose Modelling" Ulusal Medikol Fizik Kongresi, Bayrak Yayimeilik, Istanbul, 17-32, 1996.

Chuba, P.J., **Sharma, R.**, **Yudelev, M**., Duclos, M., Shamsa, F., Giacalone, S., Orton, C.G., Maughan, R.L., Forman, J.D. "Hip Stiffness Following Mixed Conformal Neutron and Photon Radiotherapy: A Dose-Volume Relationship." Int. J. Radiat. Oncol. Biol. Phys. 35, 693-699, 1996.

Alecu, R., Feldmeier, J.J., Court, W.S., **Alecu, M**., Orton, C.G. "A Model to Avoid Misadministrations in High Dose Rate Brachytherapy. Medical Phys. 24, 259-261, 1997.

Orton, C.G. "Radiobiology," In: Principles and Practice of Brachytherapy, Ed. S. Nag Futura, Armonk, New York, 27- 45, 1997.

Orton, C.G. "Fractionation: Radiobiological Principles and Clinical Practice." In: Treatment Planning in Radiation Oncology, Khan, F.M. and Potish, R.A. (eds)., Baltimore, Williams & Wilkins, 295-318, 1998.

Orton, C.G. and **Ezzell, G.A.** "Physics and Dosimetry of High Dose Rate Brachytherapy" In: Principles and Practice of Radiation Oncology (3rd Edition), Perez and Brady (eds.) J.B. Lippincott, Philadelphia, 469-485, 1998.

Narayana, V., Orton, C.G. "Pulsed brachytherapy: a Formalism to Account for the Variation in Dose Rate of the Stepping Source." Medical Physics 26, 161-165, 1999.

Orton, C.G. "High-Dose-Rate Brachytherapy may be Radiobiologically Superior to Low-Dose-Rate due to Slow Repair of Late-Responding Normal Tissue Cells." Int. J. Radiat. Oncol. Biol. Phys. 49, 183-189, 2001.

Orton, C.G. "Incorporating clinical measurements of hypoxia into tumor control modeling of prostate cancer: implications for the a/ß ratio". Int. J. Radiat. Oncology, Biology, Physics 58, 1637, 2004.

Orton, C.G. "A review of new technological developments in the radiotherapeutic treatment of cancer". IFMBE Proceedings, Vol. 7, 2004, 1 – 4.

Orton, C.G. "Radiation therapy for prostate cancer". IFMBE Proceedings, Vol. 7, 2004, 195 – 197.

STUDENTS MENTORED

STUDENT NAME		ESSAY/THESIS	YEAR
Alecu, Rodica	M.S.	Influence of the Air Cavity on Vocal Cord Treatment	1994
Aurand, Dennis	M.S.	Quality Assurance for the Beginning Medical Physicist	1994
Beideck, Daniel	M.S.	Nuclear Medicine Annual Compliance Testing	1995
Botti, James M.	M.S.	A Review of Current Methods for Acceptance Testing of Gamma Camera SPECT Systems	1994
Chen, Hann-Sen	M.S.	Lecture Planning for the Non-Curriculum Therapeutic Physicists in Taiwan	1994
Edmundson, Greg	M.S.	Implementation of Ultrasound-Based Evaluation of High Dose Rate Brachytherapy in a Commercial Three-Dimensional Treatment Planning System	1998
Edwards, Dawn	M.S.	Radiopharmaceuticals and Breast-Feeding: Radiation Doses and Recommendations	1997
Ezzell, Gary (Ph.D. Dissertation)	PhD	Genetic and Geometric Optimization of Three Dimensional Radiation Therapy Treatment Planning	1994
Fayad, Julie M.	M.S.	Computerized Tomography in Conformation Radiotherapy: An Overview of Technology and Research	1996
Gilio, Joseph	M.S.	Optimization of Conformal Therapy Treatment Planning: a New Algorithm	1995
Hu, Michael (Yuefeng)	M.S.	A Comprehensive Specification Review of the Render 3-D Computer Treatment Planning System	1994
Joyce, Melita	M.S.	A Comparison of Two Film Scanning Systems for Use in Film Dosimetry	1994
Michelle Kritzman	M.S.	Quality Control and Artifact Recognition for TCT-SPECT Systems	2000
Lectka, Tracy	M.S.	A Comparison of Various HDR vs LDR Brachytherapy Treatments of the Uterine Cervix	1994
Liengsawangwong, Praimakorn	M.S.	Quality Assurance of HDR Remote Afterloading in Bracytherapy	1994

Lo, Julie	M.S.	Sonodynamic and Photodynamic Cytotoxicity	1994
McMillan, Sharon	M.S.	Evaluating the "Effective Dose" to Normal Brain Tissue in Stereotactic Radiosurgery	1995
Metevier, Lawrence	M.S.	Review of Quality Assurance and Calibration Procedures for a High Dose Rate Afterloader	1995
Minhaj, Mohamedo	M.S.	Update on Hyperthermia in Cancer Therapy	1995
Narayana, Vrinda (Ph.D. Dissertation)	PhD	Physical and Biological Approaches to the Improvement of Dosimetry and Delivery of Brachytherapy Treatment	1997
Nathasingh, Vidia	M.S.	Cost Block Displacement: A Case Study	1995
Okafor, Joseph	M.S.	Survey of Dose Specifications in Brachytherapy	1994
Ouyang, Iris Y	M.S.	Data Acquisitions and System Setup for Render Plan 3D Radiation Treatment Planning	1995
Roberts, Walter	M.S.	A System of Monte Carlo Modelling Techniques for Clinical Problems	1994
Anurag Sharma	M.S.	Verification of Electron Beam Dosimetry	
Shen, Qiang	M.S.	Skin Reactions in Radiation Therapy	1994
Billy Shirlen	M.S.	A Review of Methods of Intensity Modulated Radio-therapy and Output Measurements for IMRT with a Varian Linac	2000
Nayyer Siddiqi	M.S.	Improvements in the Therapeutic Treatment of Cervical	2000
Stafford, Charles	M.S.	Microwave Electron Linear Accelerator History and Design	1995
Sugarman, Amy	M.S.	Treatment of Dunning R3327 Rat Prostate Tumors with Photodynamic Therapy in Combination with Fast Neutron Therapy	1995
Zhong, Dongfang	M.S.	Implementation of TG-21 Worksheet by Gupta SQL Windows	1995

STUDENTS PhD DISSERTATION COMMITTEES:

Jinho Choi
Rick Crilly
Gary Ezzell
Walter Fowler
Joseph Gilio
Kenith Hogue
Chandrasekhar Kota
Chun-Wei Li
Tom Meitzler
Vrinda Narayana
Mark Smyczynski
Mark Yudelev

COURSES TAUGHT:

RAD	501	Introductory Radiological Physics I : 1981-83, 1985, 1988-89
RAD	502	Introductory Radiological Physics II : 1984, 86
RAD	702	Radiotherapy Physics : 1983-87
RAD	704	Radiation Dosimetry : 1982, 87, 91
RAD	706	Radiobiology : 1981- 2003
RAD	707	Radiation Safety : 1994 - 2003
RAD	710	Statistics in Cancer Research : 1992

ADMINISTRATIVE COMMITTEES:

Acting Director 1984, Director, Medical Physics Graduate Programs : 1985 - 2003
Admissions Committee : 1981 - 2003
Clinical Internship Committee : 1981 - 2003
Evaluations Committee : 1981 - 2003
Graduate Committee : 1981 - 2003
Appointments and Tenure Committee : 1981 - 2003
Wayne State University Graduate Affairs Committee - 1990 - 2003
Research and Grants Committee : 1992 - 2003
Outstanding Graduate Mentor Award Committee : 1993 - 2003
Harper Hospital Library Advisory Committee : 1994 - 2003.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On March 28, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF COLIN G. ORTON, PH.D. IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on March 28, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Counterdefendants.

Case No. 08-CV-0133 RMW

DECLARATION OF WILLIAM F. GEARHART IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

REDACTED VERSION

Date: April 21, 2008
Time: 2:00 p.m.
Courtroom: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

I, William F. Gearhart, declare that:

BACKGROUND

1. The facts set forth below in this declaration are based on my personal knowledge, and if called as a witness, I could and would testify competently to those facts.

2. Since December 1999, I have been employed by SenoRx, Inc. ("SenoRx") as the Vice President for Sales and Marketing. In that role, I am responsible for the marketing and sales of SenoRx's entire product line. I supervise approximately employees, which includes a sales force working throughout the country to promote SenoRx's products. Over the past several years, I have worked to develop and implement a sales and marketing plan for the Contura™ Multi-Lumen Balloon Catheter ("Contura"). This includes assessing the potential market for post-lumpectomy radiation therapy, analyzing SenoRx's opportunity in that market, and evaluating SenoRx's competitors.

3. Prior to my position at SenoRx, I held management positions at a number of medical device companies, including Vice President, Sales and Marketing at Micro Therapeutics, a manufacturer of devices for the treatment of neuro and peripheral vascular diseases; Vice President of Sales and Marketing at Interventional Technologies, a manufacturer of devices for use in interventional cardiology; and Vice President of Sales and Marketing at Pfizer, a pharmaceutical company.

4. I received my undergraduate degree from the University of Pennsylvania, where I earned a B.S. in Business. I also received a M.B.A. from the University of Michigan and a J.D. from William Mitchell College of law.

SENORX, INC.

5. SenoRx is a small medical device company located in Orange County, California employing approximately 146 employees. SenoRx was founded in January 1998 to develop, manufacture and sell minimally-invasive medical devices for the diagnosis and treatment of breast cancer.

6. To date, SenoRx has three major product lines. First, in 2002, SenoRx introduced the Gel Mark®, a breast tissue marker which identifies the site of a biopsy for future surgical

reference. Second, in November 2005, SenoRx launched the EnCor® system, a minimally-invasive, vacuum-assisted breast biopsy system. Third, in May 2007, SenoRx received approval from the Food & Drug Administration for the Contura, which provides radiation to the surgical margins following lumpectomy for breast cancer.

7. SenoRx made its initial public offering in April 2007. SenoRx's revenue for the year ending December 31, 2007 was approximately $35 million [redacted]

THE CONTURA

8. The Contura is SenoRx's flagship therapeutic device. It is the company's first and only product for the treatment of breast cancer.

9. The Contura is pictured in Exhibit A hereto. The Contura is a balloon catheter device. Referring to Exhibit A, the balloon is labeled "A." The balloon is attached to the end of a catheter body, labeled "B." There are a number of lumens that run through the catheter body from one end of the Contura (the proximal end, "C") through to the other end (the distal end, "D"). Five of these lumens are designed to have a radiation source inserted into them; one is positioned in the center of the catheter body, and the other four are offset from the center lumen, and spaced at 90 degree increments (so that one is located above, one below, and one to either side of the central lumen). Another lumen connects to a vacuum port at the far end of the device, assisting physicians in conforming the walls of the lumpectomy cavity to the balloon by removing air and liquids from the cavity. A final lumen connects to the polyurethane balloon, and allows the balloon to be inflated and deflated.

10. The Contura received approval from the Food & Drug Administration in May 2007. After receiving FDA approval, SenoRx conducted a controlled release of the Contura to key customer accounts and industry leaders. On January 17, 2008, SenoRx announced the full commercialization of the Contura.

11. [redacted]

CONTURA PRICING

12. The Contura is priced at parity with the MammoSite. The Contura's Manufacturer Suggested Retail Price (MSRP) is $2750. [redacted].

13. [redacted]

CONTURA COMMERCIAL LAUNCH

14. [redacted] Health care professionals can easily switch between the MammoSite and the Contura. [redacted]

15. SenoRx has a policy not to promote its products off-label, and the company has reiterated to its field sales force that it should not promote the Contura inconsistent with the device label.

16. [redacted]

17. [redacted]

18. [redacted]

19. [redacted]

IMPACT ON SENORX SHOULD AN INJUNCTION ISSUE

20. [redacted] Should an injunction issue, I expect the following would occur.

21. [redacted]

22. [redacted]

23. The Contura offers the proven effectiveness of balloon brachytherapy with the additional advantage of multiple-lumens for better radiation dose control.

24.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: March 27, 2008

William F. Gearhart

Exhibit 1

Picture of the Contura MLB™ (with labels)

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On March 28, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF WILLIAM F. GEARHART IN SUPPORT OF DEFENDANT SENORX, INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION [REDACTED VERSION]

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on March 28, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Counterdefendants.

Case No. 08-CV-0133 RMW

DEFENDANT AND COUNTERCLAIMANT SENORX, INC.'S OBJECTIONS TO AND MOTION TO STRIKE CERTAIN PORTIONS OF THE DECLARATION OF GLENN MAGNUSON IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Date: April 21, 2008
Time: 2:00 p.m.
Ct. Rm: Courtroom 6, 4th Floor
Judge: Hon. Ronald M. Whyte

Pursuant to Civil Local Rule 7-5(b), Defendant and Counterclaimant SenoRx, Inc. ("SenoRx") hereby submits the following objections to, and moves to strike certain portions of, the Declaration of Glenn Magnuson in Support of Plaintiffs' Motion for Preliminary Injunction. The portions identified below are inadmissible and should be stricken for the reasons so identified.

ARGUMENT

Civil Local Rule 7-5(b) provides that "[a]n affidavit or declaration may contain only facts, must conform as much as possible to the requirements of FRCivP 56(e), and must avoid conclusions and argument." Civil L.R. 7-5(b). Federal Rule of Civil Procedure 56(e), in turn, explains that "[a] supporting or opposing affidavit must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant is competent to testify on the matters stated." Fed. R. Civ. P. 56(e) (emphasis added). The Declaration of Glenn Magnuson in Support of Plaintiffs' Motion for Preliminary Injunction ("Magnuson Decl.") contains hearsay and statements with no foundation or support. SenoRx objects to and respectfully requests that this Court strike the improper statements for the reasons identified below.

A. Statements Based on Inadmissible Hearsay Should Be Stricken (¶¶ 19, 21).

A declaration submitted under Civil Local Rule 7-5 may not contain inadmissible hearsay. *Johnson v. Peralta Community College Dist.*, No. C-94-4255, 1997 WL 227903, at *6 (N.D. Cal. Apr. 28, 1997) (striking statements from a declaration that were based on hearsay). In his Declaration, Mr. Magnuson offers two statements for the truth of the matter asserted based on the statements of unnamed sources.

First, in paragraph 19, he states that "Hologic understands from doctors approached by SenoRx that the SenoRx balloon catheter is currently priced at around $2200-$2500, which is approximately 10% to 20% less [than] the current $2750 cost of the MammoSite balloon applicator." Magnuson Decl. ¶ 19. During his deposition, Mr. Magnuson explained that he did

not remember who these doctors were. Ex. 1[1] (Magnuson Tr.), at 141:16 – 142:2 ("Q. Who did you have conversations with? A. I don't know the exact names of the physicians, but at trade shows, I've had discussions with physicians at the booth along with other representatives."). In other words, Mr. Magnuson is simply repeating the out-of-court statements of unnamed individuals. Because the statement is being offered for the truth of the matter asserted – that is, to establish the price of the Contura – it is inadmissible under Federal Rules of Evidence 801 and 802.

Second, in paragraph 21, Mr. Magnuson states that "Representatives of Hologic have been informed by several other MammoSite customers that SenoRx has approached them with sales pitches during which SenoRx directly compares the Contura System to Hologic's MammoSite system. In many instances, SenoRx attempts to undercut the MammoSite price point and/or promote the Contura MLB for off-label uses that are unproven and for which the MammoSite is (like the Contura) not approved." Magnuson Decl. ¶ 21. This statement is double hearsay. Mr. Magnuson is attempting to parrot as "fact" a statement that an unnamed source made to "representatives of Hologic," who presumably then repeated the statements to Mr. Magnuson. *See* Ex. 1 (Magnuson Tr.), at 143:7-12 ("Q. Who were the doctors that the sales reps were talking with that informed them of the prices? A. I'm not aware of specific physicians, but I've had numerous discussions with numerous sales reps and numerous sales managers and the data has been consistent.") Those statements are now being offered to establish the truth of the matter asserted. As such, they constitute inadmissible hearsay, and should be stricken from the Declaration. *See* Civil L.R. 7-5(b); Fed. R. Civ. P. 56(e) ("A supporting or opposing affidavit must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant is competent to testify on the matters stated." (emphasis added)).

---

[1] The relevant excerpts of Mr. Magnuson's deposition are attached as Exhibit 1 to the Declaration of Aaron P. Maurer in Support of Defendant's Opposition to Plaintiff's Motion for Preliminary Injunction.

B. Statements Outside the Declarant's Personal Knowledge Should Be Stricken.

A declaration must be based on facts within the declarant's personal knowledge. *See* Fed. R. Civ. P. 56(e). As stated in *Brew v. City of Emeryville*, 138 F. Supp. 2d 1217 (N.D. Cal. 2001), a declaration "must be made by witnesses having personal knowledge of the facts stated therein, state facts that would be admissible evidence, and affirmatively show that the witness would be competent to testify at trial. It is not sufficient for the declarant to state that he or she has personal knowledge of the facts stated. Rather, the declarant must state facts showing his or her connection to the matters stated, establishing the source of the information." *Id.* at 1226-27 (internal citations omitted). The Magnuson Declaration fails to meet that standard in the following instances.

1. Statements Regarding the Patents-In-Suit are Unfounded and Outside the Scope of the Declarant's Expertise (¶¶ 8, 11).

Twice in his Declaration, Mr. Magnuson opines that the MammoSite® Radiation Therapy System is patented or covered by the patents-in-suit. Magnuson Decl. ¶ 8 ("Proxima obtained patent protection on its system, including the three Patents-In-Suit. Cytyc acquired Proxima and its patented balloon brachytherapy system in March 2005 . . . ."); *id.* ¶ 11 ("The MammoSite practices technology disclosed in the Patents-in-Suit, which is directed specifically to a type of brachytherapy known as "interstitial" brachytherapy . . . ."). However, the Declaration offers no support or foundation for these claims, and Mr. Magnuson admitted during his deposition in this case that he had no personal knowledge of whether the MammoSite practiced the patents-in-suit and was offering no opinions on that issue. Ex. 1 (Magnuson Tr.), at 252:13-17 ("Q. [Y]ou are not, for purposes of this litigation or in this declaration, offering any opinion as to whether or not the patents here, Exhibits 1, 2 and 3, cover the MammoSite system? A. Correct."). Accordingly, such testimony is outside Mr. Magnuson's personal knowledge and area of expertise, and it should be stricken from the Declaration.

2. Statements Regarding the APBI Market and Medical Opinion of APBI Devices are Speculative, Unsupported, and Outside of the Declarant's Expertise (¶¶ 18, 23).

Mr. Magnuson's Declaration also contains three statements about the APBI market that are nothing more than unsupported speculation. First, in paragraph 18, Mr. Magnuson opines that "SenoRx's entry [into the APBI market], however, may cause the medical community to move away from balloon catheter systems for APBI – due at least in part to SenoRx's lack of its own clinical data to support its product. This could cause the size of the market to shrink or at least to stagnate, which would mean a permanent loss of the investment that Proxima, Cytyc and Hologic have made in the creation of this market." Magnuson Decl. ¶ 18 (emphasis added). Similarly, in paragraph 23, Mr. Magnuson speculates that "SenoRx's entry into the market with an untested product will tarnish medical opinion regarding interstitial breast brachytherapy procedures and products and could result in fewer women electing to undergo post lumpectomy treatment and thereby increasing the associated cancer recurrence rate." Magnuson Decl. ¶ 23 (emphasis added). Lastly, Mr. Magnuson states, also in paragraph 23, that "[t]he promotion of SenoRx's Contura system in a manner contrary to its labeling, and the absence of safety and effectiveness data may tarnish medical opinion regarding the use of interstitial brachytherapy procedures as a whole, including MammoSite." *Id.* (emphasis added).

These statements do not convey facts within Mr. Magnuson's personal knowledge. They are speculation about what may or could happen. This is not proper content for a declaration. *See* Civil L.R. 7-5(b); Fed. R. Civ. P. 56(e); *Ramirez v. Salvation Army*, No. C06-0631, 2008 WL 670153, at * 13 (N.D. Cal. Mar. 6, 2008) (striking from a witness's declaration statements that lacked foundation or that were not based upon sufficient facts or data, including statements in which the witness "opin[ed] that the results of the rehire interview process 'may have perpetuated an age bias'" (emphasis added)); *Luna v. Ridge*, 436 F. Supp. 2d 1163, 1167 (S.D. Cal. 2006) (striking statements from a declaration that "rely on speculation and conjecture," including paragraphs in which the declarant "abstractly theorize[d] about what might have happened during the parties' struggle and what [one of the parties] might have been thinking" (emphasis added)).

Moreover, Mr. Magnuson has no expertise to speak about how the "medical community" will view the Contura or to speculate about "medical opinion." Mr. Magnuson has no scientific or medical degrees. Ex. 1 (Magnuson Tr.), at 7:22-8:4 ("Q. Do you have any scientific degrees? A. No, I do not."). He also admitted during his deposition that, prior to assuming his current position as Plaintiffs' Senior Director of Product Marketing in July 2006, his responsibilities had nothing to do with either breast cancer treatment or brachytherapy generally. *Id.* at 12:2-8 ("Q. Prior to assuming your senior director of marketing position in July of 2006, had you had any responsibilities for breast cancer treatment? A. No. Q. Any responsibilities for brachytherapy, generally? A. No."); *see also id.* at 12:9-13:6. Thus, his statements as to the medical community and medical opinion are improper as they lack of proper foundation. *See Sega Enterprises Ltd. v. MAPHIA*, 948 F. Supp. 923, 929 (N.D. Cal. 1996) (striking a declaration where the declarant was "not qualified as an expert regarding the subject matter of the declaration"); *Benjamin v. Walt Disney Co.*, No. CV-05-2280, 2007 WL 1655783, at * 3 (C.D. Cal. June 5,2007) (striking paragraphs from a declaration where declarant "was not qualified or disclosed as an expert" to offer those opinions); *Ramirez*, 2008 WL 670153, at * 13 (striking portions of a declaration that essentially "offer[ed] argument in the guise of expert opinion").

3. Statements Regarding Why Patients and Doctors May Not Use the MammoSite are Unsupported Speculation (¶ 12).

Similarly, in paragraph 12, Mr. Magnuson states, "Thus, approximately 90,000 women each year receive more aggressive and invasive treatment for breast cancer than is medically merited, most likely because they do not know about MammoSite, or because their doctors have not had any experience with MammoSite treatment." Magnuson Decl. ¶ 12 (emphasis added). There is no foundation for Mr. Magnuson, a marketing executive with no scientific or medical degrees, to make statements about what is "medically merited" or to opine about why doctors or patients may not choose the MammoSite. Nor is he free in this context to speculate about what is "most likely," without providing any information to support that view. The information contained in this sentence does not constitute "facts" within Mr. Magnuson's "personal

knowledge," and should be stricken from the Declaration. *See* Civil L.R. 7-5(b); Fed. R. Civ. P. 56(e); *Ramirez*, 2008 WL 670153, at * 13; *Luna*, 436 F. Supp. at 1167.

4. Statements Regarding SenoRx's Supposed Reputation are Speculative and Unsupported (¶ 16).

In paragraph 16, Mr. Magnuson states that "In those markets in which SenoRx has participated, it has a reputation in the industry as carving a niche as a low-price supplier, presumably to promote faster growth and penetration into its target markets." Magnuson Decl. ¶ 16 (emphasis added). Mr. Magnuson provides no support for his assertion regarding SenoRx's supposed reputation. Indeed, he has not even listed the "markets" that are the subject of his allegation, or explained why he has any basis to opine about those markets. In any event, there is no basis for his presumption about why SenoRx may price its products a certain way. As such, this statement should be stricken from the Declaration. *See* Civil L.R. 7-5(b); Fed. R. Civ. P. 56(e); *Ramirez*, 2008 WL 670153, at * 13; *Luna*, 436 F. Supp. at 1167.

CONCLUSION

For the foregoing reasons, SenoRx objects to and respectfully requests that this Court strike the following portions of Mr. Magnuson's Declaration in Support of Plaintiffs' Motion for Preliminary Injunction: the last two sentences of paragraph 8; the first sentence of paragraph 11; the fourth sentence of paragraph 12; the entirety of paragraph 16; the fifth and sixth sentences of paragraph 18; the second sentence of paragraph 19; the entirety of paragraph 21, except for the last sentence; and the first, second, and final sentences of paragraph 23.

Dated: March 28, 2008

Respectfully submitted,

By: s/F.T. Alexandra Mahaney

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On March 28, 2008, I served a copy(ies) of the following document(s):

DEFENDANT AND COUNTERCLAIMANT SENORX, INC.'S OBJECTIONS TO AND MOTION TO STRIKE CERTAIN PORTIONS OF THE DECLARATION OF GLENN MAGNUSON IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on March 28, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
Natalie J. Morgan, State Bar No. 211143
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	Case No. C-08-0133 RMW (RS) **DEFENDANT AND COUNTERCLAIMANT SENORX, INC.'S NOTICE OF MANUAL FILING** Date: April 21, 2008 Time: 2:00 p.m. Ct. Rm: Courtroom 6, Fourth Floor Judge: Hon. Ronald M. Whyte
SENORX, INC., Counterclaimant, v. HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P., Counterdefendants.	

Regarding: **Exhibits 1, 7, 14, 15, 17, 20, 21, 22, 23, 24, 25, 26, 28 and 30 to the Declaration of Aaron P. Maurer in Support of Defendant SenoRx, Inc.'s Opposition to Plaintiffs' Motion for a Preliminary Injunction and Exhibits 4, 7 and 8 to the Declaration of Roy Weinstein in Support of Defendant SenoRx, Inc.'s Opposition to Plaintiffs' Motion for a Preliminary Injunction.**

This filing is in paper or physical form only, and is being maintained in the case file in the Clerk's office. If you are a participant in this case, this filing will be served in hard-copy shortly. For information on retrieving this filing directly from the court, please see the court's main web site at http://www.cand.uscourts.gov under Frequently Asked Questions (FAQ).

This filing was not efiled for the following reason(s):

[X] Item(s) Under Seal

Dated: March 28, 2008

Respectfully submitted,

By: s/F.T. Alexandra Mahaney

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On March 28, 2008, I served a copy(ies) of the following document(s):

DEFENDANT AND COUNTERCLAIMANT SENORX, INC.'S NOTICE OF MANUAL FILING

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on March 28, 2008.

Kirsten Blue